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Guidance for the Reregistration of Pesticide Products Containing Paraquat Dichloride as the Active Ingredient

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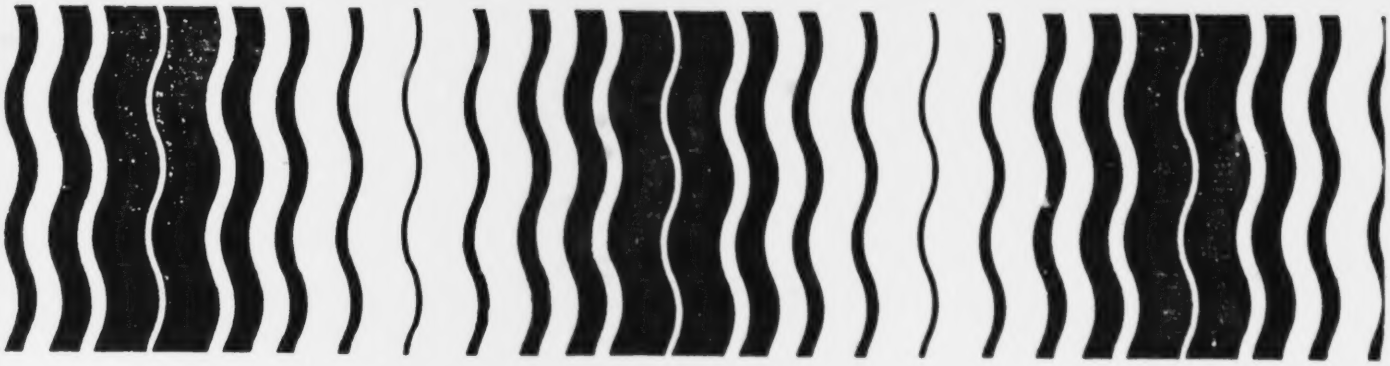
Guidance for the Reregistration of Pesticide Products Containing PARAQUAT DICHLORIDE as the Active Ingredient



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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

PARAQUAT DICHLORIDE

AS THE ACTIVE INGREDIENT

GS0262

CAS NUMBER 1910-42-5

JUNE 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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EPA Form 8580-1 - FIFRA §3(c)(2)(B) Summary Sheet
EPA Form 8580-6 - Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data
EPA Form 8580-4 - Product Specific Data Report
EPA Form 8570-27 - Generic (Formulator's) Exemption Statement

EP: End-use Product

EPA: The Environmental Protection Agency, also "the Agency"

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

Guidelines for Carcinogen Risk Assessment: The Agency's guidelines for classifying a chemical based on evidence of its carcinogenicity (September 26, 1986, 51 FR 33992). The guidelines categorize the evidence in terms of how likely it is that the chemical is a human carcinogen:

Group A - Human Carcinogen: This category is reserved for those chemicals for which there is sufficient evidence of carcinogenicity from human epidemiological studies.

Group B - Probable Human Carcinogen: This group is divided into subgroups 1 and 2. Group B1 requires some human epidemiological evidence. Group B2 is appropriate if there is "sufficient evidence" of the chemical's carcinogenicity from animal studies. "Sufficient evidence" is defined as an increased incidence of malignant (or combined malignant and benign) tumors (1) in multiple species or strains, (2) in multiple experiments, or (3) to an unusual degree with regard to incidence, site or type of tumor, or age at onset.

Group C - Possible Human Carcinogen: This group is appropriate if there is "limited evidence" of carcinogenicity in animals in the absence of human data. "Limited evidence" means that the data suggest a carcinogenic effect but are limited because (1) the studies involve a single species, strain, or experiment; or (2) the experiments are restricted by inadequate design or reporting; or (3) an increase [is seen] in the incidence of benign tumors only. Among the types of evidence which may be seen are definite malignant tumor response in a single well-conducted experiment or marginal response in a tissue known to have a high and variable background rate.

Group D - Not Classified.

Group E - This group is reserved for chemicals determined to be non-carcinogenic in animal and/or human studies.

HDT: Highest dose tested

GLOSSARY OF TERMS AND ABBREVIATIONS

The following terms are used throughout this Registration Standard and are defined here for the convenience of the reader.

ADI: (Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a complete data base.

A/D Ratio: This ratio determines a level of concern regarding whether effects observed in embryos and fetuses from treated females are "primary" (due to direct compound-related effects) or "secondary" (to maternal toxicity). Thus, the NOEL for maternal effects ("A" numerator) divided by the embryo/ fetal NOEL ("D" for "developmental"), including frank terata (gross congenital defects), defines this concern. If A/D is less than "1", developmental toxicity of a substance may be ascribed to secondary effects of maternal toxicity; if greater than 2, the substance is considered a direct (primary) developmental toxicant. Scientific interpretation is required in the range, 1 to 2 (LEL's may be used; or effects from other types of studies, e.g., reproduction).

ai: Active ingredient

CAS: Chemical Abstract Society (number)

Core Classification: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline).

Core Guideline: Studies which satisfy Agency data requirements.

Core Minimum: Studies which are acceptable to support registration of pesticide products but were not necessarily done according to Agency guidelines.

Core Supplementary: Studies in this category are scientifically sound, thus the information may be useful. However, the studies were performed under conditions that deviated substantially from recommended protocols. Studies do not meet guideline requirements and thus do not support registration of a product.

EEC: (Estimated Environmental Concentration) Estimated pesticide concentration in the environment (terrestrial or aquatic ecosystem).

TMRC: (Theoretical Maximum Residue Contribution) An estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figures for each crop. TMRC is usually expressed in terms of mg ai/day, assuming a 60 kg person.

Invalid: Studies which are deficient in some vital parameter or those studies which have been judged not to be scientifically sound or those studies whose reliability is seriously questioned.

LC_{50}: (median lethal concentration): a statistically derived concentration of a substance that can be expected to cause death in 50 percent of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/L or ppm).

LD_{50}: (median lethal dose): a statistically derived single dose that can be expected to cause death in 50 percent of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

MOS: Margin of Safety - The calculation of a margin of safety involves division of an appropriate NOEL by a worker's estimated exposure. The result is a unitless figure which gives an indication of how close a worker's internal dose is in relation to the NOEL for laboratory animals.

MPI: Maximum Permissible Intake

MRID: Master Record Identification (number)--EPA's system of tracking studies used in support of registrations

MP: Manufacturing-use product

NPDES: National Pollution Discharge Elimination System

NOEL: No Observed Effect Level--the maximum dose used in a test which produces no observed adverse effects.

OPP: The Office of Pesticide Programs (EPA)

OES: Office of Endangered Species, U.S. Fish and Wildlife Service

OM: Organic matter (used to describe soils)

ppm: Parts per million

PADI: (Provisional Acceptable Daily Intake) An acceptable daily intake of pesticide residue based on a limited data base.

PAI: Pure active ingredient

Technical: Active ingredient as manufactured

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

Common Name : Paraquat dichloride

Chemical Name : 1,1'-dimethyl-4,4'-bipyridinium ion

Empirical Formula : $C_{12}H_{14}Cl_2N_2$(dichloride)

Trade Name : Cekuquat, Crisquat, Herboxone, Gramuron, Dextrone, Dexuron, Esgram, Gramaxone, Gramanol, Herbaxon, Goldquat 276, Pillaquat, Paracol, Paraquat Cl, Pillarxene, Sweep, Actor, PP148 (dichloride) and Dextrone X.

OPP/Shaugnessy No. : 061601 (dichloride)

Chemical Abstract Service (CAS) Registry No. : 1910-42-5 (dichloride)

B. USE PROFILE

Type of Pesticide : Contact herbicide, desiccant, defoliant, or plant growth regulator

Pest Controlled : Weeds or other vegetation

Registered Uses : Cropland, noncropland, forestry ornamentals, and turf

Predominant Use : Field crops (corn and soybeans)

Method of Application : Broadcast, band, or directed spray by ground equipment, or aircraft

Mode of Activity : Lipid peroxidation resulting in disruption of cell membrane

Formulation -

Manufacturing-Use Product : 29.1% and 43.5% active ingredient

End-Use Product : Soluble concentrates, pressurized liquids

C. HISTORY

Paraquat was discovered in 1882 and has been used as an oxidation-reduction indicator under the name of methyl virologen since 1932. The first commercial paraquat formulation for agricultural use was produced by Imperial Chemical Industries, Ltd. in England and was registered there in 1962. It was registered in the United States in 1964.

Paraquat was accepted as a candidate for the Rebuttable Presumption Against Registration (RPAR) process in 1978 and an intense scientific review of the paraquat data base was initiated. The Agency identified the following areas where paraquat was believed to exceed the risk criteria under 40 CFR 162.11: teratogenicity, lack of emergency treatment, chronic effects, reproductive effects, oncogenicity (data gap), mutagenicity (data gap), and acute effects. Other areas of concern include mammalian toxicity and avian reproductive effects.

A Paraquat Decision Document was issued in October 1982 (43 FR 30613) in which the Agency concluded that available data did not support an RPAR in relation to the criteria identified in 1978. To date, all other areas of concern have been evaluated and none of the risk criteria have been exceeded. (Note: Under the current Special Review criteria, the risk criterion for acute inhalation has not been exceeded. Paraquat has the potential to cause adverse effects but the Agency believes it does not because the generated droplets are not respirable.)

After the RPAR review, the Agency believed that the acute effects level was very close to estimated applicator exposures. However, the significance of this could not be interpreted without additional dermal and inhalation data and more precise information relating to applicator exposure. These data have since been called in and have been evaluated for this document.

The following lists the data that have been required under FIFRA section 3(c)(2)(B) since the 1982 Decision Document:

Groundwater Data Call In (DCI)

- Degradation studies - Lab
  - hydrolysis
  - photodegradation (water, soil)
- Soil metabolism study - Lab
  - aerobic soil
  - anaerobic soil
- Mobility studies -
  - leaching
  - adsorption
  - desorption
- Field dissipation study -
  - soil
  - forestry areas
- Water solubility
- Vapor pressure
- Octanol water partition coefficient

DCI from Decision Document

Nondietary exposure

- Worker/applicator exposure
- Face-mask filtration capacity

Spray particle size for field application techniques

Acute inhalation

21-Day subchronic dermal study

Mutagenicity studies

New study or additional information for an earlier study -

- Chronic feeding study (rats)
- Oncogenicity study (rats)
- Reproduction study

The regulatory conclusions regarding these data and the relationship to the concerns of 1982 Decision Document are discussed in the Agency Assessments section.

One significant result of the Decision Document was that the registrant voluntarily cancelled certain noncrop uses including rights of way. These use patterns had the potential to cause problems with birds and mammals. Currently, the only anticipated wildlife problems are with endangered species and the Agency believes that label statements will be adequate to protect endangered plants and animals.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all data, submitted to support the registration of paraquat, available through June 1, 1985. Several toxicological studies received after this date have been reviewed and, therefore, included in this Standard. Based on the review of these data, the Agency has reached the following conclusions. A discussion of this review follows this summary section.

Tolerance Reassessment. The ADI (acceptable daily intake) has been set using a recent more sensitive study. The ADI is based on a 1-year dog feeding study (MRID 00132474) with a NOEL (no-observed-effect level) of 0.45 mg/kg/day. Applying a safety factor of 100 results in an ADI of 0.0045 mg/kg/day and a maximum permissible intake (MPI) of 0.27 mg/kg/day (for a 60 kg person). The theoretical maximum residue contribution (TMRC), the total of all published tolerances, is 0.1134 mg/day. The TMRC constitutes 42 percent of the MPI.

Toxicological Assessment. With the exception of an inhalation study, the toxicology data base is complete. Paraquat is extremely toxic to mammals (Category I) by all routes of exposure; however, it is noted that inhalation toxicity is dependent on particle size. Based on positive findings in the rat, the Agency has classified paraquat as a Group C oncogen (Possible Human Carcinogen), in accordance with Agency Guidelines for Carcinogen Risk Assessment (September 26, 1986, 51 FR 33992).

Worker Exposure Analysis. Quantitative exposures to workers (mixers, loaders, and applicators) were estimated using data called in after the Decision Document.

Worker Safety Calculations. The margins of safety (NOEL/exposure) appear adequate for all workers.

Hazard Assessment for Terrestrial and Aquatic Organisms and Endangered Species. Based on available information, the Agency does not anticipate that wildlife populations, excluding endangered species, will be adversely affected when paraquat is used according to label directions. As a result of consultations with the Office of Endangered Species (OES), only one bird, the Attwater's greater prairie chicken, and several plants were determined to be in potential jeopardy for certain uses.

As a result of this determination, labeling to protect endangered species is required for all end-use products used for treatment of crops, rangeland and pastures. This labeling is addressed in Pesticide Registration (PR) Notices 87-4 and 87-5, issued May 1, 1987.

Environmental Fate Assessment. Environmental fate data were evaluated for compliance with current data requirements. The available data indicate that paraquat will not leach in agricultural soils. The major degradate (QINA) has a potential for leaching. Data deficiencies were identified and additional data are required to fill the data gaps.

Review of Product Chemistry Data. Product chemistry data were evaluated for compliance with current data requirements. Data deficiencies were identified and additional data required to fill the data gaps.

Analysis of Paraquat's Restricted-Use Classification. All agricultural products will retain the restricted-use classification. One homeowner end-use product containing 0.276 percent paraquat cation available to the public on a unrestricted basis will continue to be unrestricted.

Analysis of Current Label Statements. The warning statements that currently appear on paraquat labels were evaluated to determine if they were appropriate and adequately protected workers and the environment. In addition to label statements required by Part 162.10, statements in the following areas have been added.

- Restricted use classification
- Worker safety statements
- Grazing and feeding restrictions

As a result of this review, the Agency has identified missing data which are necessary to evaluate risks associated with the use of paraquat. These data must be developed in order to maintain registrations of products or register new products containing paraquat. The following table summarizes the data gaps. Please note that this is only a summary, and more details can be obtained by referring to the data tables.

SUMMARY OF DATA GAPS - PARAQUAT

Environmental Fate:	Photodegradation (water) Aerobic and anaerobic soil metabolism Leaching and adsorption/desorption Terrestrial and conditional long-term field dissipation studies Rotational crops Aquatic nontarget organism
Toxicology :	90-Day inhalation
Residue Chemistry :	Storage stability of paraquat in animal tissues Support data for various commodities New enforcement analytical methodology
Product Chemistry	

B. TOLERANCE REASSESSMENT

Tolerances have been established for residues of paraquat on a wide variety of raw agricultural commodities, in meat, fat, and meat byproducts of animals (40 CFR 180.205), in processed food (21 CFR 193.331), and in feed (21 CFR 561.289) derived from raw agricultural commodities.

1. Residue Data. The residue data reviewed in support of these tolerances include:

   a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of paraquat. The terminal residue of concern is paraquat per se. Tolerances are set on the parent compound only.

   b. Radiolabeled studies on the uptake, translocation, and metabolism of paraquat in plants show that paraquat is not measurably metabolized by plants.

   c. Radiolabeled studies on the metabolism and translocation of paraquat in pigs, goats, cattle, poultry, and rats.

   d. Analytical methodology for determining the levels of residues of paraquat in plants and animals. Such methods have been determined to be suitable for residue determinations but not for enforcement purposes.

   e. Storage stability data demonstrating that residues of paraquat are stable in plant samples for up to 5 months. Similar data on animal products to support the results of animal feeding studies have not been submitted.

   f. Data on the magnitude and levels of residues in individual raw agricultural commodities, animal products, and processed food and feed items.

At the same time that the Agency evaluated the data supporting tolerances, EPA also determined whether:

- All use patterns (including those registered under FIFRA section 24(c) and intrastate uses) and methods of application are supported by existing tolerances;

- The existing uses of paraquat require the establishment of tolerances in animal products because of residues that may transfer to animals from feed items derived from raw agricultural commodities;

- Food additive tolerances are necessary because residues in the raw agricultural commodities concentrate in processing;

- Crop group tolerances could be established in accordance with 40 CFR 180.34(f);

- In the absence of certain tolerances, restrictions on use, grazing or feeding are necessary; and

- The tolerances are expressed accurately and in current terminology.

2. Dietary Assessment. The toxicity data considered to establish an ADI include:

   a. A 1-year feeding study in dogs, with a NOEL of 0.45 mg/kg/day. This study was selected as the basis for the ADI. A safety factor of 100 results in an ADI of 0.0045 mg/kg/day and a MPI of 0.27 mg/day (for a 60 kg individual).

   b. A chronic feeding/oncogenicity study in rats, with a NOEL of slightly below 25 ppm or 1.25 mg/kg/day. This study was rejected as the basis for the ADI for two reasons.

      (1) The NOEL of the dog study is slightly lower.

      (2) The lowest dose (25 ppm) approximates the systemic NOEL. Twenty-five ppm is an approximate NOEL because some minor lenticular changes at or near the end of the study were observed at that level. If this study were used for the ADI calculation, a higher safety factor would have to be used to compensate for these effects. If a safety factor as high as 300 were to be used with this rat study, it would approximate the ADI resulting from the dog study. Thus, the dog study yields a more conservative ADI.

The TMRC for paraquat, based on published tolerances, is 0.1134 mg/day. The TMRC constitutes 42 percent of the MPI. Daily dietary exposure to paraquat, therefore, is less than the calculated acceptable daily intake for humans.

C. TOXICOLOGICAL ASSESSMENTS

Acute Oral and Dermal Toxicity. Acute toxicity studies show that via the oral and dermal routes, paraquat is extremely toxic (Category I) (Toxicity categories are discussed in 40 CFR 162.10.) Symptoms of toxicity associated with oral and dermal acute exposure include lethargy, weakness, diarrhea, wheezing, bloody nose, anorexia, adipsia, anoxia, hyperpnea, tachycardia, cyanosis, and pulmonary changes.

Acute Inhalation Toxicity. In the 1982 Decision Document, the Agency determined that the acute inhalation toxicity data available at that time were inadequate and insufficient to provide a definitive conclusion with respect to acute inhalation toxicity. Additional data were required.

In 1985, two new acute inhalation toxicity studies on rats were received. One was performed using aerosolized paraquat with more than 90 percent of the particle diameters below 0.3 um. The LC_{50} for this study was a range of 0.6-1.4 ug/L (Toxicity Category I). The second study was performed using aerosolized paraquat particles with a median diameter of 21.5 to 23 um, with about 0.2 percent less than 2.5 um. The LC_{50} for this study was approximately 3.5 ug/L (Toxicity Category I). The difference in LC_{50} values between these two studies can be explained by the difference in particle sizes reaching the alveolar region of the lung.

In the first study, virtually all the particles were small enough to reach the lung alveoli and be absorbed. In the second study, only a small percentage of the total particles were small enough to reach the alveoli. The inverse relationship between inhalation toxicity and particle size, within limits, is a well-known toxicological phenomenon. (The topic of pulmonary disposition is discussed in Toxicology, the Basic Science of Poisons, edited by L. Casarett and J. Doull, published by McMillan Publishing Company, Inc., New York, 1975.)

Also in 1985, the Agency received some laboratory information on the particle size of paraquat droplets that might be formed during aerial application and knapsack spraying. Virtually no droplets smaller than 15 um were formed for either method of application. The Agency does not expect that the field application droplet spectrum will significantly differ from the droplet spectrum found in the laboratory studies. Therefore, EPA believes that the two acute inhalation studies described above overestimate the potential acute inhalation hazard to workers.

Irritation and Sensitization (Eye and Dermal). Paraquat causes severe eye irritation (Category I) in male rabbits. Symptoms reported after exposure to 0.1 ml of test material included complete opacity in 3 of 6 rabbits tested: purulent discharge ran from the eyes into the mouth, causing severe burning of the mucosa and inability to eat. A severe burning of the nasal mucosa was also seen in most rabbits. Other studies show paraquat to be a moderate dermal irritant (Category III). Signs of toxicity included: slight to severe erythema and very slight to slight edema in most rabbits; hemorrhaging edematous lungs, discolored grainy livers, soft vascularized kidneys and decreased body fat in some rabbits. A dermal sensitization study in guinea pigs shows paraquat not to be a skin sensitizer.

Subchronic Toxicity. In the 1982 Decision Document, margins of safety for workers repeatedly exposed to paraquat were calculated based upon the results of two subchronic inhalation studies, each with a NOEL of 0.01 ug/L. The particle size of aerosolized paraquat in one of the studies was 2 um. Although not specifically stated, it is assumed that the particle size in the other study was also about 2 um. The 1982 Decision Document also noted, however, that such small particle sizes were an unlikely occurrence in the field and that realistic margins of safety would probably be greater. Data available at that time did not allow establishment of margins of safety consistent with actual use. Furthermore, margins of safety relating to repeated dermal exposure of workers were not presented in the 1982 Decision Document because the available subchronic dermal data were inadequate and dermal absorption rate studies were not available.

Additional inhalation and dermal data on worker exposures were required to be submitted to the Agency. Determinations of particle sizes of paraquat droplets formed during application were also required to be submitted. In addition, subchronic dermal data and dermal absorption rate data were also required.

All the required information has now been submitted to and evaluated by the Agency.

The available subchronic toxicity data for paraquat include a 90-day feeding study with dogs, a 21-day dermal study with rabbits, and two 3-week inhalation studies with rats. Dermal absorption data on humans are also available.

The 90-day dog feeding study is adequate. The NOEL in that study is 20 ppm (0.5 mg paraquat cation/kg bwt) and the LEL (lowest effect level) is 60 ppm (1.5 mg of paraquat cation/kg bwt). The toxic signs at the 60 ppm level were alveolitis, increased lung weight, and alveolar collapse.

The 21-day dermal study with rabbits demonstrated a NOEL of 1.15 mg paraquat cation/kg bwt with respect to localized skin effects at the sites of application (inflammation; ulceration, scabbing and acanthosis). No evidence of systemic toxicity was observed in this study at dosage levels up to and including 6.0 mg paraquat cation/kg bwt, the highest dosage level tested.

The two 3-week inhalation studies, previously used in the 1982 Decision Document to calculate margins of safety for workers used aerosolized paraquat particles of about 2 um. The Agency now has information generated in the laboratory indicating that during aerial application or knapsack spraying virtually no paraquat particles $\leq$ 15 um are formed. Since particles > 15 um are not inhalable, the Agency has now decided that it would be inappropriate to use these studies to calculate margins of safety for workers. The results of recently submitted acute inhalation studies with paraquat, in which toxicity was observed to be inversely related to particle size, also support the decision.

The two old 3-week inhalation studies were also deficient in that attention was focused primarily on effects on the respiratory organs/tissues and inadequate evaluation of systemic toxicity in other organs/tissues was performed. To more fully assess the potential inhalation hazard to workers repeatedly exposed to paraquat, the Agency is requiring submission of a 90-day inhalation study which will assess not only respiratory but also other systemic toxicities in test animals exposed to paraquat aerosols. The final protocol for this study is to be determined in consultation with the Agency when the results of particle size studies under field conditions are available. A 90-day study, rather than a 3-week study, is required in order to fully evaluate the potential long-term toxicity of paraquat exposure to workers repeatedly exposed to paraquat over extended periods of time.

The Agency now has acceptable dermal absorption data derived, in part, from studies on humans. These data indicate that about 0.5 percent of paraquat is absorbed through the skin over a 24-hour exposure period. Inasmuch as dermal data from humans are preferable to dermal data from other species, the Agency has used the dermal absorption rate of 0.5 percent together with recently submitted dermal exposure data to determine dermal absorption of paraquat by workers regularly exposed to paraquat by the dermal route of exposure. Inhalation exposure was also determined for these same groups of workers based on recently submitted inhalation exposure data and an assumed inhalation absorption rate of 100 percent. Finally, absorption for combined dermal and inhalation exposures was also determined. Margins of safety for workers regularly exposed to paraquat were then calculated by relating dermal absorption and inhalation absorption separately and then combined to the NOEL of 0.5 mg paraquat cation/kg bwt/day derived from the 90-day dog feeding study described previously. The results are presented in Table 1.

In all cases except two, the combined dermal and inhalation margins of safety are greater than 100 and are considered by the Agency as adequate for protection of workers. In two instances, margins of safety for combined dermal and inhalation exposures

Table 1. Margins of Safety for Subchronic Hazard to Workers
(Combined Dermal and Inhalation Exposure)

Use/Worker	Daily Dermal From Lunchick EAB (11/22/85) (ug/kg/day)	Exposure Adjusted for dermal absorp. (ug/kg/day)	Margin of Safety†	Daily Inhalation Exposure (from Lunchick ug/kg/day)	Margin of Safety†	Daily Dermal Plus Inhal. Exposure (ug/kg/day)	Margin of Safety†
Directed sprays in Orchards, Vineyards, Windbreaks, Shade and Ornamental Trees							
Ground Boom							
Low Acreage*	63	0.32	1600	0.69	720	1.01	500
High Acreage*	290	1.45	340	3.10	160	4.55	110
Hand-Held Spray Gun							
Low Acreage*	57	0.29	1700	0.04	13000	0.33	1500
High Acreage*	260	1.30	380	0.16	3100	1.46	340
Ground Boom Application to Field Crops (Corn, Soybeans, Sorghum, Wheat)							
Individual Farmers*	820	4.10	120	2.50	200	6.60	80
Commercial Contractors							
Mixer/Loader (only)	750	3.75	130	0.30	1700	4.05	120
Applicator (only)	69	0.35	1400	2.20	230	2.55	200
Aerial Application to Field Crops (Corn, Soybeans Sorghum, Wheat)							
Mixer/Loader (only)	79	0.40	1300	0.26	1900	0.66	760
Pilot (only)	29	0.15	3300	0.77	650	0.92	540
Flagger - with resp. prot.	160	0.80	630	0.77	650	1.57	320
Flagger - no resp. prot.	160	0.80	630	7.70	65	8.50	60
Aerial application to Cotton (Defoliant Use)							
Mixer/Loader (only)	20	0.10	5000	0.05	10000	0.15	3300
Pilot (only)	7	0.04	3000	0.18	2800	0.22	2300
Flagger-with resp. prot.	38	0.19	2600	0.18	2800	0.37	1400
Flagger-no resp. prot.	38	0.19	2600	1.80	280	1.99	250
Work Exposure During Noncrop Uses							
Large Sites*	290	1.45	340	3.10	160	4.55	110
Small Sites*	280	1.40	360	0.14	3600	1.54	330

Table 1. Margins of Safety for Subchronic Hazard to Workers Dermal and Inhalation Exposure (cont'd).

Use/Worker	Daily Dermal Exposure		Margin of Safety†	Daily Inhal. Exposure (fr.Lunchick ug/kg/day)	Margin of Safety†	Daily Dermal Plus Inhal. Exposure (ug/kg/day)	Margin of Safety†
	From Lunchick EAB (11/22/85) (ug/kg/day)	Adjusted for dermal absorp. (ug/kg/day)					
Ground Boom Application to Cotton (Defoliant Use)††							
Mixer/Loader (early season)	34	0.17	2900	0.01	50000	0.18	2800
Mixer/Loader (late season)	250	1.25	400	0.07	7100	1.32	380
Applicator (early season)	9	0.05	10000	0.30	1700	0.35	1400
Applicator (late season)	35	0.18	2800	1.10	450	1.28	390
Ground Boom Application to Cotton (Dessication Use)††							
Mixer/Loader (Minimum)	270	1.35	370	0.08	6300	1.43	350
Mixer/Loader (Maximum	810	4.05	120	0.13	3800	4.18	120
Applicator (Minimum)	46	0.23	220	1.50	330	1.73	290
Applicator (Maximum)	74	0.37	140	2.40	210	2.77	180
Worker Exposure During Use on Range, Pasture and Forage Crops	Not Greater than Use on Field Crops						
Worker Exposure During Resin Soaking	Not Greater than "Backpack" use in Orchards, etc.						
Worker Exposure During Tree Injection						0.06**	8300

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*Mixer/Loader plus applicator.

†Calculated by dividing NOEL of 500 ug/kg/day (from a 90-day feeding study in dogs) by the daily combined dermal and inhalation exposures of workers.

**From Lunchick, EAB (February 10, 1986).

††From Lunchick, EAB (January 28, 1986).

In its 1982 Decision Document, the Agency determined that the available reproductive data were inadequate. A two-generation reproduction study was required. An adequate study has now been submitted. Technical paraquat dichloride had no effect on reproduction in the Wistar-derived Alderley Park strain of rats in a three-generation study. The levels of paraquat cation fed were 25, 75, and 150 ppm. An increased incidence of alveolar histiocytosis in the lungs of male and female parents was noted at the 75 ppm level resulting in a systemic NOEL of 25 ppm. Since the NOEL for this study is higher than that from the dog study used to calculate the ADI an adequate margin of safety (> 100) exists with respect to human exposure.

Chronic Toxicity. In the 1982 Decision Document, the Agency determined that the available chronic toxicity data were inadequate. Chronic toxicity studies consisting of two oral feeding studies (dog and rat) were requested and subsequently submitted to the Agency. The new data, which are adequate, are summarized below.

In the 1-year dog study, Alderley Park beagle dogs were fed 0, 15, 30, and 50 ppm paraquat cation. The systemic NOEL is 15 ppm (0.45 mg of paraquat cation/kg bwt). The systemic LEL is 30 ppm (moderately increased severity and extent of chronic pneumonitis). The NOEL from this study was used to calculate the ADI for human dietary exposure to paraquat.

In a combined toxicity and carcinogenicity study in rats (113 to 126 weeks), 25, 75 and 150 ppm paraquat cation were fed to Fischer 344 strain of rats. Although very slight effects (mostly lenticular changes) were observed at the 25 ppm level in both sexes, they occurred mostly after 104 weeks of treatment. Until that time, or through most of the life span of the animals, a NOEL was in fact 25 ppm. Toxic symptoms observed at the 75 ppm level included an increased incidence of opacities, cataracts, and nonneoplastic lung lesions (alveolar macrophages and epithelialization, and slight peribronchilar lymphoid hyperplasia). The Agency considers the NOEL for this study to be slightly below 25 ppm (1.25 mg paraquat cation/kg bwt). Although very slight toxicity was observed in this study at the lowest dosage level tested, the effect was not considered by the Agency to be serious enough to warrant requiring a new study, particularly since the dog study described has a NOEL of about one-half that observed in the rat study.

Oncogenicity. In the 1982 Decision Document, the Agency determined that the available oncogenicity data were inadequate. Two oncogenic studies (rat and mouse) were requested and subsequently submitted to the Agency. These studies are summarized below:

In the mouse oncogenic study, paraquat was not oncogenic to male or female Alderley Park strain mice under the conditions of this study. The levels of paraquat cation fed for 97 to 99 weeks were 12.5, 37.5, and 100/125 ppm of paraquat cation. (Initially, the highest level fed was 100 ppm, but it was changed to 125 ppm in the 36th week of testing because no toxic signs appeared at that level.) The systemic NOEL for non-oncogenic effects was 12.5 ppm (1.87 mg paraquat cation/kg bwt). This study is adequate.

In the combined toxicity and carcinogenicity study in Fischer 344 strain of rats discussed above under "Chronic Toxicity," the interpretation of the lung lesions was difficult. The Agency received three interpretations of the histopathology of the lungs in the rat study. Review of the submitted data by one pathologist indicated an increase in the incidence of pulmonary neoplasms (adenomas and carcinomas, but especially adenomas) in lungs of male and female rats. However, a histopathology report by a second pathologist, who reexamined the same lung slides, did not indicate an oncogenic effect attributable to the administration of paraquat. The third pathologist found that the incidence of pulmonary adenomas and carcinomas did not show a relationship to treatment with paraquat.

Other dose-unrelated tumor types observed included pituitary, thyroid and adrenal glands, all within the range reported for historical controls.

There was an increase of incidences of pancreatic islet cell adenomas (mid-dose), mammary gland benign fibroepithelial and testis interstitial cell tumors (high dose) over concurrent controls in male rats. Malignant lymphomas were also increased in males; however, based on the Agency's review, it was a relatively small elevation, dose-unrelated and could not be attributed to the compound. At the high dose in male rats, there was an increase over concurrent controls in the incidence of lipomas of the skin and subcutis. None of these increases in incidences of tumors were statistically significant.

Squamous cell carcinoma was a predominant tumor in the head region of the male and female rats. This uncommon tumor occurred in 51.6 percent of all rats having tumors of the skin and subcutis in the head region. In high dose males, the incidence of this tumor was significantly increased over concurrent controls. However, since the rats were group-housed, exposure other than oral due to scratching and/or fighting cannot be excluded.

The Agency has, based on this rat study and other data discussed in this section, classified paraquat as a Group C oncogen (Possible Human Carcinogen) in accordance with the Agency's Guidelines for Carcinogen Risk Assessment. These guidelines categorize the evidence of carcinogenicity of chemicals in terms of how likely it is that the chemical is a human carcinogen. Under this scheme, Group C categorization is appropriate if there is "limited evidence" of the chemical's carcinogenicity from animal studies. "Limited evidence" is defined as studies that:

- involve a single species, strain, or experiment and do not meet the criteria for "sufficient evidence" (...to an unusual degree in a single experiment with respect to high incidence, unusual site or type of tumor, or early age of onset);
- are restricted by inadequate dosage levels, inadequate duration of exposure to agent, inadequate period of follow up, poor survival, two few animals, or inadequate reporting; or
- show an increase in the incidence of benign tumors only.

The Agency has concluded that the data presently available for paraquat provides limited evidence of oncogenicity in animals, in that there is only one study with one species (rat) and one strain (Fischer 344) with positive findings (skin tumors in high-dose males only). Although the type of tumor was considered to be uncommon, it was not of unusually high incidence nor did it appear early. A quantitative estimation of the oncogenic potential is not justified by the weight-of-evidence: there is limited evidence of oncogenicity in a single sex, strain, and species in one study with an adequate negative study in a second species (mice).

Mutagenicity. In its 1982 Decision Document, EPA determined the available mutagenicity data were inadequate. Additional data were required and have been submitted to the Agency. The evaluation of mutagenic properties of paraquat is based on 21 studies as follows:

a. Nine gene mutation assays: *S. typhimurium* TA 92, 98, 10, 1535, 1537, 1538 and G 46 his-strains; *A. nidulans* strains 35 and P_3; and L5178Y mouse lymphoma cells in culture.

b. Five structural chromosome aberration assays: dominant lethal (Charles River CDI mice and Swiss-Webster mice); cytogenic (human lymphocytes and bone marrow of Wistar rats); and micronucleus test in mice.

c. Seven DNA damage/repair assays: *S. typhimurium* TA 1978 and 1538 strains; *Sacch. cerevisiae* D4, JDI and "other" strains; human embryo epithelial cells; rat hepatocytes in culture; and sister chromatid exchange in Chinese hamster lung fibroblasts.

Based on review of these data, the Agency has concluded that paraquat was negative in eight studies (mostly in gene mutation and chromosomal aberration assays); weakly positive in four studies (two gene mutation, one chromosomal aberration and one DNA damage/repair assays); and positive in four studies (all DNA damage/repair assays). Five studies (three gene mutation, one chromosomal aberration and one DNA damage/repair) were not acceptable.

Based on these studies, paraquat is considered weakly genotoxic. Additional mutagenicity studies are not required.

Metabolism. Paraquat dichloride or paraquat dimethyl sulfate (radiochemical purity: 99.3-99.8 percent), labeled with ^{14}C, in either methyl groups or in the ring, was poorly absorbed from the gastrointestinal tract of mammals and was excreted in feces mostly as unchanged paraquat. However, after an oral dose, there was microbial degradation of paraquat in the gut. (In one study with rats, 30 percent of a dose of paraquat appeared in feces in a degraded form.) A portion of these microbial degradation products can be absorbed and be excreted in urine, whereas the remainder is excreted in feces.

In studies with cows and rats, about 96 percent and 70 to 96 percent, respectively, of the administered radioactivity (single oral doses) was excreted in feces within 2 to 3 days as unchanged paraquat. In studies with a goat and pigs, in which ^{14}C-labeled paraquat was administered orally for 7 consecutive days, 50 percent and 70 percent, respectively, of the total radioactivity was recovered in feces, also as unchanged paraquat. In a study with a goat, 33 percent of the radioactive dose was also present in the contents of the digestive tract, but these determinations were not made for pigs after the animals were killed.

However, in studies in which ^{14}C-methyl labeled paraquat was administered subcutaneously to rats or was injected intramuscularly into monkeys, 70 to 80 percent and 59 percent, respectively, of the radioactivity was recovered in urine as unchanged paraquat. Most of this radioactivity was eliminated in 24 hours after dosing.

The distribution of radioactivity was studied in the heart, brain, liver, kidneys, muscle (forequarter and hindquarter), blood, fat (peritioneal and subcutaneous), and lungs of goats and pigs. Expressed as ug (micrograms) of paraquat ion/g of tissue, most of the radioactivity was found in lungs, kidneys and liver. With the exception of liver and peritoneal fat, the radioactivity in all tissues studied was associated with unchanged paraquat. In the liver, about 3 percent of the radioactivity was associated with 4-(1,2-dihydro-1-methyl-2-oxo-4-pyridyl)-1-methylpyridinium ion (compound I or monopyridone) and about 3 to 4 percent of the radioactivity was associated with 1-methyl-4-(4-pyridyl) pyridinium ion (compound II or monoquat). Peritoneal fat contained about 6.5 percent of the radioactivity in that tissue as monoquat. Similar findings were observed in studies with rats. Paraquat accumulated in the lungs of goats and rats, but not pigs. Additional metabolism studies are not required.

Miscellaneous Studies. Three studies contribute significantly to an overall assessment of paraquat toxicity. These are: 1) acute dermal absorption study with humans; 2) urinary excretion study in monkeys; and 3) oral corrosion potential study with rabbits.

In the first study, single doses of ^{14}C-methyl-labeled paraquat (99.8 percent pure) were applied on the forearms, hands and legs of six adult male volunteers (age 30 to 74), and absorption was measured by determining total ^{14}C in urine. Absorption was very slow from all application sites (average values of 0.23 to 0.29 percent of the dose during 5 days after dosing).

In the second study, monkeys injected intramuscularly with paraquat eliminated 58.6 percent of the dose in the urine within 7 days.

The figures for average human absorption (0.23 to 0.29) in the table below are corrected for the recovery of 58.6 percent of the administered dose in the monkeys. However, taking into account the great variations in the human urinary excretion of ^{14}C-paraquat (see range in table below showing up to 0.702 percent dermal absorption) and the fact that only urinary excretion of ^{14}C was measured, a 0.5% dermal absorption rate is considered to be a reasonable figure to use in estimating dermal exposure in the margin of safety calculations.

Site of Dermal Applications	Human Urinary Excretion of ^{14}C (% of the applied dose)		
	Average	Standard Deviation	Range
Forearm	0.293	0.117	0.205-0.519
Back of Hand	0.230	0.078	0.123-0.341
Lower Leg	0.285	0.232	0.052-0.702

In the third study, 1 ml aliquots of paraquat dichloride (28.6 percent a.i.) and its aqueous dilutions ranging from 1:2 to 1:200 were applied to the tongue of New Zealand strain rabbits. Dilutions as small as 1:100 were corrosive to the tongue. Other affected tissues were larynx, lungs, liver, and kidneys. In the case of lungs, necrotizing pneumonia, congestion/edema, and pulmonary hemorrhage were reported. Laryngeal lesions were also observed at the 1:200 dilutions.

Lack of Emergency Treatment. The Agency indicated in its 1982 Decision Document that both the oral administration and skin absorption of paraquat have been responsible for poisoning incidents. Case histories from accidental poisonings indicated that varying amounts of paraquat are lethal (from a sip to several mouthfuls); death is generally caused by pulmonary insufficiency; and accidents are frequently the result of storage in unmarked bottles. Case histories from accidental dermal exposures demonstrated that paraquat can be percutaneously absorbed in amounts sufficient to cause death.

The Agency believed at that time that the therapeutic approach to treatment of acute oral exposure is only partially effective. The 81 percent survival rate occurring in case histories available to the Agency in combination with rapid availability of treatment information (provided by placement of a 24-hour emergency treatment telephone number on all labeling) suggests an adequate emergency treatment for accidental oral ingestion. The Agency is now requiring that information for adequate emergency medical treatment (such as a 24-hour emergency telephone number) appear on the labels of all end-use products (EPs) containing paraquat. On April 14, 1982, the Agency established an exemption from the requirement of tolerance for an emetic that is incorporated into paraquat formulations. The emetic is intended to induce rapid vomiting, thereby reducing the absorption of paraquat. The Agency is continuing to require that the emetic (or other emetic of equally suitable properties and clearness) be incorporated into all formulations of paraquat.

In the 1982 Decision Document the Agency noted that relatively few dermal exposure cases have resulted in fatalities from paraquat products. With the exception of a homeowner use product containing a very low concentration of active ingredient, all products bear Restricted Use Classification. Applicators of such products are required to undergo training in the safe handling of pesticides and receive instruction in product labeling and labeling interpretation. Current paraquat product labeling instructions include exposure reduction techniques for mixers and applicators. Mixers are instructed to "wear a full face shield, rubber gloves and apron" while applicators facing a risk of exposure are instructed to "wear goggles and approved face mask capable of filtering spray droplets." They are also instructed to "wear waterproof footwear and clothing when spraying or when contacting vegetation wet with spray." The Agency believes that the precautionary measures dictated by current labeling are adequate for prevention of acute dermal toxicity.

Worker Exposure Analysis. An assessment was conducted of workers exposed to paraquat, which estimated worker exposure during different application techniques. The exposure estimates were derived from surrogate data, corrected for paraquat's use rates, and additional data submitted by the registrant(s). Three different application techniques were initially evaluated: aerial, ground boom, and hand spraying. A fourth technique, tree injection, was subsequently evaluated. The application techniques and usage scenarios have large ranges in exposure rates or hours of exposure, which is normal for a herbicide with numerous use patterns. Therefore, many of the exposure estimates are presented as a mean with its corresponding range. All of the exposure estimates were unadjusted for dermal or respiratory absorption rates; however, this adjustment was made during the process of estimating margins of safety.

Specific exposure information and a discussion of the studies used are available in the science support document, Exposure Estimates for Registered Uses of Paraquat, and its addendum.

Margins of Safety. Margins of safety (MOSs) were calculated for workers using paraquat. The calculation involves division of an appropriate NOEL by a worker's estimated exposure. The result is a unitless figure which gives an indication of how close a worker's internal dose is in relation to the NOEL for laboratory animals.

Daily dermal exposures were adjusted for a dermal absorption rate of 0.5 percent by dividing the exposure by 200. Daily inhalation exposures were not adjusted, i.e., a 100 percent absorption rate was assumed. MOSs were calculated for dermal and inhalation exposure separately and then for combined dermal and inhalation exposures by relating these values to a NOEL of 0.5 mg/kg/day (500 ug/kg/day) derived from a 90-day subchronic feeding study in dogs. The LEL in this study was 1.5 mg/kg/day at which dosage level toxic effects in the lung were observed.

All MOSs are considered adequate. Only two worker groups have an MOS less than 100. Individual farmers who mix/load and apply paraquat by ground boom application to field crops have an MOS of 80. Flaggers with no respiratory protection working in field crops being aerially sprayed with paraquat have an MOS of 60. All other workers have an MOS greater than 100. More detailed information is available in the preceding discussion of subchronic toxicity.

D. OTHER SCIENCE FINDINGS

Hazard Assessment for Aquatic Organisms. Paraquat would not normally be expected to present a hazard to fish or aquatic invertebrates at expected rates up to 1.0 lb ai/A. Available acute toxicity data indicate that paraquat is slightly toxic to certain species of fish and moderately toxic to daphnid. This is based on a 96-hour LC_{50} of 13 ppm for bluegill and a 48-hour LC_{50} values for daphnia ranging from 1.2 ppm to 8.0 ppm. Initial exposure of aquatic organisms to paraquat, based on direct application to water 6 inches deep at rates ranging from 0.25 to 1.0 lb ai/A would be expected to range from 0.184 to 0.734 ppm. This results in at least at twofold margin of safety for fish (based on 1/10 the LC_{50}) and approximates the LC_{50} for aquatic invertebrates. Paraquat, however, is not applied directly to water. Terrestrial use of paraquat would result in less contamination of water and a greater margin of safety. Paraquat appears to tightly bind to most soils and is not expected to runoff.

Hazard Assessment for Terrestrial Organisms. There is no evidence to suggest that the use of paraquat has either resulted in kills or has affected mammalian or avian populations. Data suggest that mammals, especially lagomorphs, feeding on freshly sprayed vegetation and eggs of ground-nesting birds sprayed with paraquat would be affected most. The Agency does not expect either of these to occur with high frequency. Mammals are unlikely to feed on a site immediately after spraying. With respect to the potential for paraquat to have toxic effects on bird's eggs, some embryo mortality could result when paraquat replaces cultivation and ground-nesting birds are allowed to continue to brood and eggs receive a direct hit. However, most, if not all, uses of paraquat are either not applied during avian egg laying season; are applied under conditions not conducive to laying eggs on the ground; or would not allow ground-nesting birds to continue their brooding.

Endangered Species Hazard Assessment. The Agency has consulted with the Office of Endangered Species (OES) regarding endangered species concerns. As a result of this consultation, only one bird and several plants were determined to be in potential jeopardy.

Because of species use patterns and relative moderate toxicity, no mammals were determined to be in jeopardy. The only avian species for which it was determined there may be a "may affect" situation is the Attwater's greater prairie chicken. There may be situations when this ground-nesting bird's eggs would be sprayed with paraquat when it is applied to existing ground cover in corn. Paraquat use on corn creates a potential for affecting up to 41 percent of the total prairie chicken population. In addition, since paraquat is a nonselective herbicide, plants which are associated with grassland habitats or any other habitat to which paraquat can be applied could potentially be exposed to paraquat.

As a reasonable and prudent alternative, if paraquat is not used in the range of the Attwater's greater prairie chicken, or within or adjacent to the habitat of numerous plants identified by OES, jeopardy will be avoided. Therefore, labeling to protect endangered species is required for all end-use products used for treatment of crops, rangeland, and pastures. This labeling is addressed in PR Notices 87-4 and 87-5, dated May 1, 1987.

Environmental Fate. A review of the data indicates that only the hydrolysis and photodegradation in soil requirements are fulfilled. Paraquat dichloride was stable to hydrolysis at 25°C and 40°C at pH 5, 7, and 9 for up to 30 days. Other data indicate that paraquat has a half life of > 2 weeks in water plus soil, is immobile in silt loam and silty clay loam and slightly mobile in sandy loam soils. Adsorption of paraquat is positively correlated with soil cation exchange capacity and is not readily desorbed from soil organic matter and clay. Paraquat does not leach except in sand and does not volatilize. Based on the information available paraquat should not reach groundwater. The paraquat degradate (QINA) is very loosely absorbed on the organic matter/clay complex and, therefore, has a potential for groundwater contamination. The additional data required are set forth in Table A, Appendix I. Once these data are received, the potential for groundwater contamination will be reevaluated.

In response to the groundwater data call in, the Agency was referred to a number of existing studies, and additional studies were received and reviewed by the Agency. The additional data, however, resulted in the filling of only one additional data requirement--photodegradation on soil.

Product Chemistry. The available data have been evaluated which identify the ingredients, identify the materials and manufacturing process and discuss the physical and chemical properties of the technical grade of the active ingredient and the manufacturing-use product. Specific data requirements have been identified and are listed in the data table.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on paraquat, the Agency has made the following determinations. Where label revisions are specified, specific language is set forth in Section D of this chapter.

1. None of the risk criteria listed in Section 154.7 of Title 40 of the Code of Federal Regulations (40 CFR 154.7) for initiating a special review have been met. Therefore, paraquat is not being placed in special review at this time.

   Rationale. After considering data submitted concerning acute inhalation, subchronic toxicity, and chronic toxicity, the Agency has determined that no reason exists for placement of paraquat into special review status.

   Although paraquat has been found to be an oncogen, as discussed in the Agency Assessment section, the Agency does not believe, at this time, that it meets the criteria requiring a special review. The regulations provide that the Administrator may conduct a special review if a pesticide use "may pose a risk of inducing in humans an oncogenic . . . effect, which is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk."

   After considering applicator exposure to paraquat, also discussed in the Agency Assessment section, the Agency has concluded that the risks posed by paraquat are not of concern, in terms of the magnitude of risk, to the individual applicator.

2. The Agency is continuing to require that an emetic cleared under 40 CFR 180.1065 be incorporated into all MPs and EPs containing paraquat.

   Rationale. Based on the history of poisoning by accidental ingestion of paraquat and partial effectiveness of therapeutic treatment after exposure, the Agency determined that an emetic is needed in the formulations to induce rapid vomiting, thereby reducing absorption of paraquat.

3. The Agency is requiring that information for adequate, rapid emergency medical treatment (such as a 24-hour emergency telephone number) for accidental oral ingestion of paraquat appear on all EPs containing paraquat.

Rationale. Case histories of accidental oral ingestion of paraquat available to the Agency indicate that a higher survival rate (81%) is achieved when emergency medical treatment information is rapidly available (such as when an emergency telephone number or other treatment information appears on the label).

4. The Agency is requiring that those products or formulations already classified as "Restricted Use" and labeled with worker safety rules maintain these label statements and "Restricted Use" classification.

Rationale. The available acute oral, dermal, inhalation, and ocular data indicate that the toxicity category for these formulations is I. Based on the high acute toxicity to animals and people from intentional or inadvertent exposure, those formulations were classified as "Restricted Use." The Agency believes that the "Restricted Use" classification and current precautionary labeling are necessary to continue to protect mixer/loaders and applicators from effects of dermal and inhalation toxicity.

5. The Agency has determined that the 0.276 percent paraquat formulation available to the public on an unrestricted basis will continue to be unrestricted.

Rationale. This formulation is Toxicity Category IV in acute studies with rats and Toxicity Category III in acute dermal and inhalation studies with rabbits. When used according to the label directions, the formulation is not likely to present a significant health hazard to humans.

6. The Agency will not require additional residue data on the following raw agricultural commodities (RACs): carrots, potatoes, turnips, onions, broccoli, cabbage, cauliflower, apricots, peaches, strawberries, acerola, bananas, guava, mint hay, safflower, oats, chinese cabbage, collards, lettuce, rhubarb, guar, lima beans, snap beans, cherries, plums, wheat, asparagus, coffee beans, hops, papayas, sorghum grain, bean forage, pea forage, apples, pears, nectarines, small fruits, almond hulls, avocados, cottonseed, kiwifruit, passion fruit, sugarcane, sorghum forage, pistachios, and sunflower; the following animal products: meat and fat of cattle,

meat, fat, and meat byproducts of other livestock and milk; and the following crop groupings: fruiting vegetables (except cucurbits), citrus fruits, and tree nuts.

Rationale. The Agency has determined that the available residue data adequately support the established tolerances for these RACs and animal products.

7. The Agency is requiring additional residue data on the following RACs: sugar beets, bean hay, sweet corn, alfalfa, pineapple, range grass, rye, sugar beet tops, pea hay, field corn, clover, figs, pasture grass, turnip tops, cucurbit vegetables, corn forage and fodder, trefoil, soybean forage, hay and straw, sorghum silage and hay, wheat hay and straw; meat byproducts of poultry and eggs; and on processed foods derived from the following RACs: potatoes, sugar beets, tomatoes, wheat, coffee beans, plums, figs, alfalfa, spent hops, olives, pineapples, and sugarcane. Refer to Table A for details on type of data required.

   Rationale. A review of the available data indicates that the Agency does not have sufficient residue data to support the established tolerances for paraquat on the above commodities.

8. The Agency requires residue data together with a petition for establishing tolerances, if necessary, for cotton forage and sugarcane forage. Alternatively, a statement may be placed on the label prohibiting the grazing or feeding of treated commodities. Each registrant will have 6 months to notify the Agency which alternative it chooses. Refer to Table A for details of residue data required.

   Rationale. Review of the available data indicates that the residue data are required to cover the possible transfer of residue to animals from the feed items.

9. The Agency will require an increased tolerance of 0.1 ppm for olives. Alternatively, a statement may be placed on the label prohibiting application when olives on the ground are to be harvested. Each registrant will have 6 months to notify the Agency as to which alternative it has selected.

   Rationale. The available residue data indicate that the 0.05 ppm tolerance level is too low because higher residues occur in fruit that comes in contact with treated soil or vegetation. Increasing the tolerance for olives from

0.05 to 0.1 ppm would increase the theoretical maximum residue concentration (TMRC) by only 0.04 percent, which represents a negligible increase in risk due to dietary exposure.

10. The Agency will not establish any new food/feed additive regulations pursuant to Section 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA) and is deferring action on previously established food/feed additive regulations.

Rationale. The Delaney Clause in Section 409 of the FFDCA bars the establishment of food/feed additive regulations for substances that induce cancer in man or test animals, with certain exceptions. The Agency is currently developing a position relative to the Delaney Clause and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Once this policy has been established, the Agency will determine what action is required in relation to pesticides that have produced oncogenic responses in chronic animal studies.

11. The Agency will propose the following technical changes in the listing of paraquat tolerance.

a. The listings for "pea forage" and "bean forage" will be changed to "pea hay" and "bean hay."

b. The listing for "small fruits" will be changed to read "small fruits (excluding strawberries and cranberries)."

c. The listing for "hop vines" will be deleted.

Rationale. The above changes are required because:

a. The terms "bean hay" and "pea hay" are currently used instead of "bean forage" and "pea forage."

b. The existing tolerance for strawberries is five times that for other small fruits and will be listed separately. The use directions for cranberries vary significantly from the use directions for the remaining small fruits.

c. The listing for "hop vines" is unnecessary because the Agency has determined that hop vines are neither an RAC nor an animal feed item.

12. The Agency will establish the following group tolerances if requested by the registrants: brassica leafy vegetables, pome fruits, and stone fruits.

Rationale. Available residue data on existing members of the groups are adequate to support such group tolerances, and the uses and tolerances within the group are substantially similar as required by 40 CFR 180.34(f).

13. The Agency has determined that the following group tolerances cannot be set: root and tuber group, leaves of root and tuber group, bulb vegetables, leafy vegetables (except brassica), legume vegetables, foliage of legume vegetables, cereal grains, forage, fodder, hay and straw of cereal grains, and nongrass animal feeds.

Rationale. The reasons why group tolerances are not appropriate are described for each group in Table A, but include the following: residue data are not available for designated representative crops, use patterns are not sufficiently similar, or maximum residues vary by a factor of more than 5.

14. The Agency is requiring that uses for paraquat on ground-cherry and garlic be deleted from the labeling of all EPs.

Rationale. The uses on ground-cherry and garlic are not supported by tolerances.

15. The Agency will require a label restriction for figs prohibiting application when figs on the ground are to be harvested.

Rationale. The available data do not support the established tolerance level of 0.05 ppm on figs because higher residues were found in figs harvested from the treated ground.

16. Label use directions for the following crops require label statements prohibiting grazing or feeding of the treated crop or cover crop: barley hay and straw, oat hay and straw, citrus crop grouping (cover crop), tree nuts group (cover crop), avocado (cover crop), figs (cover crop), guava (cover crop), and pistachios (cover crop).

Rationale. A review of Agency files indicates that no data exist to support tolerances necessary for grazing of listed crops and cover crops.

17. The Agency is requiring that grazing restrictions be deleted from product labels for the use patterns on range grass, pasture grass, alfalfa, birdsfoot trefoil, clover, and field corn.

Rationale. The Agency has determined that a grazing restriction for these treated commodities is not practicable. This change will not result in a significant increase in the existing TMRC and thus will not appreciably increase the risk to humans due to dietary exposure.

18. The Agency is not requiring a reentry interval for currently registered uses of paraquat. The current reentry label statements will continue to be required on all EPs.

Rationale. The Agency has reviewed the available information on the registered uses of paraquat and the cropping practices in those crops. The potential for fieldworker exposure to paraquat residues appears to be very low; i.e., for the current registered uses, agricultural practices in those crops do not involve fieldworkers in prolonged, substantial contact with pesticide-treated surfaces. Therefore, the Agency does not require submission of reentry data as detailed in 40 CFR 158.140. The Agency reserves the right to require such data in the future if a change in registration or agricultural practices would cause substantial exposure for field workers. The Agency has also determined that current precautionary labeling and worker safety rules are adequate to protect the mixer/loader/applicator from exposure.

19. The Agency is not requiring a ground water advisory statement for products containing paraquat.

Rationale. Available data indicate that paraquat is immobile in silt loam and silty clay loam and slightly mobile in sandy loam soils. Paraquat is not readily desorbed from soil and does not leach in agricultural soils. There is a potential for the QINA degradate to leach in soils because it is loosely absorbed to organic matter and clay. Additional data are required to further determine this potential.

20. The Agency is requiring labeling to protect endangered species for all EPs used for treatment of crops, rangeland, and pasture. This labeling is addressed in PR Notices 87-4 and 87-5.

Rationale. Although available data and information on habits of various species of animals indicate that paraquat will not cause problems with stable wildlife populations, its acute and subchronic toxicity may be hazardous to unstable or endangered populations. Consultation with the OES indicated that these populations may be in jeopardy in areas treated with paraquat.

21. While the data gaps are being filled, currently registered MPs and EPs containing paraquat as the sole active ingredient may be sold, distributed, formulated, and used in the United States, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the data tables, in order to maintain existing registrations.

The Agency will issue registrations for substantially similar products. New uses will be considered on a case-by-case basis.

Rationale. Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sections 3(c)(2)(B) and 3(c)(7)).

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated and the Agency will determine if the data will affect the registration of paraquat.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain paraquat as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

Product Composition Standard. To be registered or reregistered under this Standard, MPs must contain paraquat as the sole active ingredient. Each MP formulation proposed for registration must be fully described with appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients that are present in products, as well as impurities found at greater than 0.1 percent.

Acute Toxicity Limits. The Agency will consider registration of technical-grade products and MPs containing paraquat provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which the product is placed.

Use Patterns. To be registered under this Standard, MPs must be labeled for formulation into EPs for registered uses, as listed in the Use Index, Appendix III.

D. LABELING

All products must bear appropriate labeling as specified in 40 CFR 162.10. The labels of all products must also bear the appropriate disposal statements. See Appendix II for specific information regarding label requirements.

In order to remain in compliance with FIFRA, no pesticide product containing paraquat may be released for shipment by the registrant after July 1, 1989, unless the product bears an amended label that complies with the requirements of this Standard.

In order to remain in compliance with FIFRA, no pesticide product containing paraquat may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after July 1, 1990, unless the product bears an amended label that complies with the requirements of this Standard.

In addition to the above, in order to remain in compliance with FIFRA, the following information must appear on the labeling:

1. Ingredient Statement. This ingredient statement for MPs_____ must list the active ingredient as:

   Paraquat dichloride, 1,1'-dimethyl-4,4'-
   bipyridinium ion . . . . (% ai)

2. Use Pattern Statements. All MPs must state that they are intended for formulation into EPs for acceptable use patterns. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

3. Precautionary Statements

Manufacturing-Use Products. Labels of all MPs must bear the statement:

> This pesticide is toxic to wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in a National Pollutant Discharge Elimination System (NPDES) permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of EPA.

End-Use Products

a. All formulated EPs must bear the following statement:

> This pesticide is toxic to wildlife. Do not apply directly to water or wetlands (swamps, bogs, marshes and potholes). Do not clean equipment washwaters in a manner that will contaminate water resources.

b. Labels of all products classified for restricted use must bear the following statement:

> RESTRICTED USE PESTICIDE. For retail sale to and use only by Certified Applicators or persons under their supervision and only for those uses covered by the Certified Applicator's certification.

c. Labels of all EPs must bear information for adequate, rapid emergency medical treatment (from accidental oral ingestion) such as an emergency telephone number or other emergency treatment information.

d. Labels of all products registered for use on oats and barley must bear the following statement:

> Do not graze livestock, treated oats or barley. Do not feed treated oats and barley to livestock.

e. Labels for all products registered for use on citrus, tree nuts, avocados, guava, and pistachios must bear the following statement:

> Do not graze treated area. Do not feed cover crops grown in treated areas to livestock.

f. Labels for all products registered for use on figs must bear the following statements:

> Do not graze treated areas or feed cover crops grown in treated areas to livestock.
>
> Do not apply paraquat when figs to be harvested are on the ground.

g. The use for ground-cherry and garlic, and the grazing and feeding restriction for the use patterns of range grass, pasture grass, alfalfa, birdsfoot trefoil, clover, and field corn must be deleted from product labels.

h. All EPs labeled for use on agricultural crops must bear the following statements:

> Worker Safety Rules/Reentry Statements
>
> USE STRICTLY IN ACCORDANCE WITH DANGER STATEMENTS AND DIRECTIONS, AND WITH APPLICABLE STATE AND FEDERAL REGULATIONS.
>
> DO NOT get on skin, eyes or clothing. DO NOT inhale spray mist. WASH SPLASHES from skin and eyes immediately. REMOVE and wash contaminated clothing. WASH before eating, smoking and drinking. WEAR full face shield, rubber gloves, apron and waterproof footwear when handling or mixing concentrate. WEAR waterproof footwear and clothing when spraying or when contacting vegetation wet with spray.
>
> DO NOT enter treated areas without protective clothing until sprays have dried. AVOID working in spray mist. If there is risk of exposure wear goggles and approved face mask capable of filtering spray droplets.

KEEP all unprotected persons out of operating areas or vicinity where there may be danger of drift. Certain States may require more restrictive reentry intervals; consult your State Department of Agriculture for further information. Written or oral warnings regarding use of protective clothing and accidental exposure must be given to workers who are expected to be in treated areas or in areas about to be treated.

IMPORTANT: The effect of swallowing paraquat is more severe than the effect from skin contact or from inhaling spray mist. This product should not cause injury if used according to label instructions. Follow the label as if your life depends on it.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B[2].
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. _You request a waiver of the data requirement._ If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. _You request that EPA amend your registration by deleting the uses for which the data are needed._ You are not required to submit data for uses which are no longer on your label.

6. _You request voluntary cancellation of the registration of your product(s) for which the data are needed._

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

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I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Robert J. Taylor (PM 25)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

APPENDIX I

DATA TABLES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE TECHNICAL

Guideline Citation and Name of Test	Test Substance[1]	Guidelines Status[1]	Are Data Required Yes	No	Footnote Number	Data Must Be Submitted Within Timeframe Listed Below[2]
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	TGAI	R	☐	☒		
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	R	☒	☐	3, 4	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	R	☒	☐	5	6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	CR	☒	☐	6	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	R	☒	☐		6 Months
63-3 - Physical State	TGAI	R	☒	☐		6 Months
63-4 - Odor	TGAI	R	☒	☐		6 Months
63-5 - Melting Point	TGAI	R	☒	☐		6 Months
63-6 - Boiling Point	TGAI	R	☒	☐		6 Months

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TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE TECHNICAL

Guideline Citation and Name of Test	Test Substance1/	Guidelines Status1/	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Timeframe Listed Below2/
§158.120 Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	☒	☐		6 Months
63-8 - Solubility	TGAI or PAI	R	☒	☐		6 Months
63-9 - Vapor Pressure	PAI	R	☐	☒		
63-10 - Dissociation Constant	PAI	R	☐	☒		
63-11 - Octanol/Water Partition Coefficient	PAI	R	☐	☒		
63-12 - pH	TGAI	R	☒	☐		6 Months
63-13 - Stability	TGAI	R	☒	☐		6 Months
Other Requirements						
64-1 - Submittal of Samples	TGAI, PAI	CR	☐	☒		

: :

1/ TGAI = Technical Grade of the Active Ingredient (the Agency considers the TGAI to be the dried technical salt). PAI = Pure Active Ingredient; R = Required; CR = Conditionally Required.

2/ Data must be submitted within the indicated timeframe based on the date of the Guidance Document.

TABLE A

GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE TECHNICAL

§158.120 Product Chemistry (cont'd)

3/ Details of the manufacturing process including the relative amounts of beginning materials; a description of the equipment used to produce the product reaction conditions; the duration of each step of the process; purification procedures; and quality control measures are needed.

4/ The name and address of the manufacturer, producer, and supplier of each beginning material used to manufacture technical are needed. Also, a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties must be submitted.

5/ A discussion of each impurity believed to be present at $\geq$ 0.1%, based on knowledge of beginning materials, possible chemical reactions, and any contamination present, is required.

6/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at $\geq$ 0.1% (w/w) using valid analytical methods.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)?	Timeframe for Data Submission[2]
§158.125 Residue Chemistry					
171-2 - Chemical Identity	TGAI	Yes	00113684 00113715	No	
171-3 - Directions for Use	--	Yes	Registered Label	No	
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Yes	00065602 00091378 00065604 00114411 00091365 00114414 00091366	No	
- Livestock	PAIRA and Plant Metabolites	Yes	00028596 00089748 00028597 00114414 00028598 00114422 00028599 00117783	No[3]	
171-4 - Residue Analytical Method					
- Plant residues	TGAI and Metabolites	Partially	00025269 00114421 00030476 00114446 00032141 00114453 00032240 00114465 00037058 00114466 00090400 00138258 00112663 00162742 00114411 00162743	Yes[4]	24 Months
- Animal residues	TGAI and Metabolites	Partially	00036306 00114421 00037058 00114422 00112663	Yes[5]	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]/
§158.125 Residue Chemistry (cont'd)				
171-4 - Storage Stability Data	PAI	Partially	00037057 00113702	Yes[6]/ 15 Months
171-4 - Magnitude of Residue--Residue Studies for Each Food Use				
- Root and Tuber Vegetables Group[7]/				
- Carrots	TEP	Yes	00030476	No
- Potatoes	TEP	Yes	00033612 00091376 00105060	No
- Potato chips	EP	No		Yes[8]/ 24 Months
- Potato granules	EP	No		Yes[8]/ 24 Months
- Potato (dried)	EP	No		Yes[8]/ 24 Months
- Sugar beet roots	TEP	Partially	00113709	Yes[9]/ 24 Months
- Processed sugar beets (dehydrated pulp, molasses, and sugar)	EP	No		Yes[10]/ 24 Months
- Turnip roots	TEP	Yes	00030476	No
- Leaves of Root and Tuber Vegetables Group[11]/				
- Sugar beet tops	TEP	Partially	00113709	Yes[12]/ 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]/
§158.125 Residue Chemistry (cont'd)				
- Turnip tops	TEP	Partially	00030476	Yes[13]/ 24 Months
- Bulb Vegetables Group[14]/				
- Onions	TEP	Yes	00113680 00136330	No
- Leafy Vegetables (except Brassica vegetables) Group[15]/				
- Lettuce	TEP	Yes	00114474 00139741	No
- Rhubarb	TEP	Yes	00031863	No
- Brassica Leafy Vegetables Group[16]/				
- Broccoli	TEP	Yes	00103245	No
- Cabbage	TEP	Yes	00030476	No
- Cauliflower	TEP	Yes	00030476	No
- Chinese Cabbage	TEP	Yes	00030476	No
- Collards	TEP	Yes	00030476	No
- Legume Vegetables Group[17]/				
- Beans (succulent, lima, and snap)	TEP	Yes	00030476 00033223	No

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]
§158.125 Residue Chemistry (cont'd)				
- Guar	TEP	Yes	00114420	No
- Peas (succulent)	TEP	Yes	00030476	No
- Soybeans	TEP	Yes	00015768 00015769 00015770 00015771 00015772 00015773 00015774 00015775 00025268 00030676 00031742 00032427 00033530 00034112 00098579 00109728 00114446	No[18]
- Soybean hulls	EP	Yes	00015768 00015769 00015770 00015771 00015772 00015773 00015774 00015775 00025268 00030676 00031742 00032427 00033530 00034112 00098579 00109728 00114446	No[19]
- Foliage of Legume Vegetable Group[20]				
- Bean vines and hay	TEP	Partially	00030476 00033223	Yes[21] 24 Months
- Pea vines and hay	TEP	Partially	00030476	Yes[22] 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation		Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2/]
§158.125 Residue Chemistry (cont'd)					
- Soybean forage and hay	TEP	Partially	00015768 00015769 00015770 00015771 00015772 00015773 00015774 00015775	00025268 00030676 00032427 00033530 00034112 00098579 00109728	Yes[23/] 24 Months
- Fruiting Vegetables (except cucurbits) Group[24/]	TEP	Yes	00030476 00033223 00059596		No
- Processed tomatoes (wet and dry pomace, puree, catsup, and juice)	EP	No			Yes[25/] 24 Months
- Cucurbit Vegetables Group	TEP	Partially	00027988 00030476 00033223		Yes[26/] 24 Months
- Citrus Fruits Group	TEP	Yes	00023329 00027298 00033695 00035665	00070779 00070780 00113821	No[27/]
- Pome Fruits Group[28/]					
- Apples	TEP	Yes	00033695 00035664 00070779 00113821		No

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]/
§158.125 Residue Chemistry (cont'd)				
- Pears	TEP	Yes	00033695 00035664 00113821	No
- Stone Fruits Group[29]/				
- Apricots	TEP	Yes	00035663 00113821	No
- Cherries	TEP	Yes	00023329 00027965 00033695 00113821	No
- Nectarines	TEP	Yes	00035663 00113821	No
- Peaches	TEP	Yes	00023329 00023883 00027695 00033035 00033694 00033695 00035663 00070780 00070784 00113709 00113821	No
- Plums	TEP	Yes	00023329 00033035 00033695 00035663 00113709 00114436	No
- Dried prunes	EP	No		Yes[30]/ 24 Months
- Small Fruits and Berries Group[31]/	TEP	Yes	00023329 00023883 00027968 00033695 00070780 00113709 00113821 00114411 00138258	No

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation		Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2/]
§158.125 Residue Chemistry (cont'd)					
- Tree Nuts Group[32/]	TEP	Yes	00023329 00023883 00027971 00030929 00033695	00035666 00070780 00113821 GS0262-004	No
- Cereal Grains Group[33/]					
- Barley grain	TEP	Yes	00114411		No
- Corn, field and fresh (including sweet kernels, plus cob with husks removed)	TEP	Partially	00015751 00015752 00015955 00016441 00016442 00016444 00016445 00023131	00023512 00030647 00030683 00031744 00033223 00093182 00114426	Yes[34/] 24 Months
- Corn milled products	EP	Partially	00015751 00015752 00015955 00016441 00016442 00016444 00016445 00023131	00023512 00030647 00030683 00031744 00033223 00093182 00114426	Yes[35/] 24 Months
- Oat Grain	TEP	Yes	00114411		No
- Oat milled products	EP	No			No[36/]

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]/
§158.125 Residue Chemistry (cont'd)				
- Rice Grain[37]/				
- Rye Grain	TEP	No		Yes[38]/ 24 Months
- Sorghum Grain	TEP	Yes	00023131 00070872 00026963 00113709 00027178 00114421 00033223	No
- Sorghum milling fractions (except flour)	EP	Partially	00114421	Yes[39]/ 24 Months
- Wheat Grain	TEP	Yes	00027311 00113693 00114411 00140828	No
- Wheat milled fractions	EP	No		Yes[40]/ 24 Months
- Forage, Fodder, Hay, and Straw of Ceral Grains Group[41]/				
- Barley hay and straw	TEP	Partially	00114411	No[42]/
- Corn forage, silage, and fodder	TEP	Partially	00015751 00027972 00015752 00027973 00015955 00030647 00016441 00030683 00016442 00031519 00016444 00031744 00016445 00033208 00023131 00033223 00023512 00093182	Yes[43]/ 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2/]
§158.125 Residue Chemistry (cont'd)				
- Oat hay and straw	TEP	Partially	00114411	No[44/]
- Rice straw[45/]				
- Sorghum forage, fodder, silage, and hay	TEP	Partially	00026963 00027178 00070872	Yes[46/] 24 Months
- Wheat hay, and straw	TEP	Partially	00027311 00114411	Yes[47/] 24 Months
- Grass Forage, Fodder, and Hay Group	TEP	Partially	00033223 00058773 00114424 00114466 00117783	Yes[48/] 24 Months
- Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay) Group[49/]				
- Alfalfa	TEP	Partially	00032140 00058774 00105061 00114405 00114421 00114424 00114464 00114465 00114467 00126671 00128624	Yes[50/] 24 Months
- Alfalfa meal	EP	No		Yes[51/] 24 Months
- Birdsfoot Trefoil	TEP	Partially	00114424	Yes[52/] 24 Months
- Clover	TEP	Partially	00114424 00117783	Yes[53/] 24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]
§158.125 Residue Chemistry (cont'd)				
- Crown Vetch[54]				
- Miscellaneous Commodities				
- Acerola	TEP	Yes	00128221	No
- Asparagus	TEP	Yes	00033532 00113675	No
- Avocados	TEP	Yes	GS0262-006	No[55]
- Bananas	TEP	Yes	00113709 00139733	No
- Coffee beans	TEP	Yes	00139734	No
- Processed products (roasted beans and instant coffee)	EP	No		Yes[56] 24 Months
- Cottonseed	TEP	Yes	00031739 00033612 00091372	No
- Cotton forage	TEP	No		Yes[57] 24 Months
- Figs	TEP	Partially	00139735	Yes[58] 24 Months
- Dried figs	EP	No		Yes[59] 24 Months
- Guava	TEP	Yes	00114419	No[60]

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]
§158.125 Residue Chemistry (cont'd)				
- Hops	TEP	Yes	00113686	No
- Hop Vines	TEP	Yes	00113686	No[61]
- Spent Hops	EP	No	-	Yes[62] 24 Months
- Hops (dried)	EP	Yes	00113686	No[63]
- Kiwifruit	TEP	Yes	00088195	No
- Mint hay	TEP	Yes	00137859	No
- Spent Mint Hay	EP	Yes	00137859	No
- Olives	TEP	Yes	00139737	No[64]
- Olive Oil	EP	No	-	Yes[65] 24 Months
- Papaya	TEP	Yes	00033695	No
- Passion Fruit	TEP	Yes	00037056	No
- Pineapple	TEP	Yes	00114411	No[66]
- Pineapple Forage	TEP	Yes	00114411	No[67]
- Pineapple Juice	EP	No	-	Yes[68]
- Pineapple Bran	EP	No	-	Yes[68]

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]
§158.125 Residue Chemistry (cont'd)				
- Pistachios	TEP	Yes	00027550 00113699	No[69]
- Safflower Seed	TEP	Yes	00114411	No
- Sugarcane	TEP	Yes	00114411 00114469	No
- Sugarcane Forage	TEP	No	-	Yes[70] 24 Months
- Sugarcane bagasse	EP	Yes	00114411 00114469	No[71]
- Sugarcane juice	EP	Yes	00114411 00114469	No[71]
- Sugarcane molasses refined sugar	EP	No		Yes[72] 24 Months
- Sunflower Seed	TEP	Yes	00106570 00114422	No
- Sunflower meal	EP	Yes	00106570	No[73]
- Sunflower seed hulls	EP	Yes	00106570	No[74]
171-4 - Magnitude of Residues in Meat, Milk, Poultry, and Eggs				
- Milk	TGAI or Plant Metabolites	Yes	00090978 00114414 00114422 00117783	No

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[2]/
§158.125 Residue Chemistry (cont'd)				
- Meat, Fat, and Meat Byproducts of Pigs	TGAI or Plant Metabolites	Yes	00036305 00114414 00114422 00117783	No
- Meat and Fat of Cattle	TGAI or Plant Metabolites	Yes	00090978 00114414 00114422 00117783	No
- Meat Byproducts of Cattle		No	-	Yes[75]/ 18 Months
- Meat, Fat, and Meat Byproducts of Poultry	TGAI or Plant Metabolites	No	-	Yes[76]/ 18 Months
- Eggs	TGAI or Plant Metabolites	Partially	00038503	Yes[76]/ 18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

3/ If the toxicology review concludes that any of the metabolites, occurring in animals along with paraquat, are of concern, additional methodology as well as revision of the tolerance regulation for meat, milk, poultry, and eggs will be required.

4/ Current methodology is acceptable for obtaining residue data but is only minimally adequate for enforcement/monitoring purposes due to the fact that it is too long and cumbersome. The length of procedure is caused by long digestion times, use of ion-exchange columns, and the fact that the determination step is colorimetric. New methodology is required which allows faster determination of paraquat in raw agricultural commodities and food.

5/ If review of the toxicology information conclude that metabolites occurring in animals are of toxicological significance, additional methodology including validation data and sample chromatograms, as well as completion of a successful method trial for the metabolites of concern, will be needed.

6/ No data are available concerning the storage stability of paraquat residues in animal commodities. The following data are required:

- o Data reflecting the stability of paraquat residues of concern in animal tissues stored at freezing temperatures for time intervals approximately those of the samples of animal tissues and products from treated animals used in animal feeding studies to determine the magnitude of the residue.
- o All residue data requested in this Standard must be accompanied by data regarding storage length and conditions of storage of samples analyzed. These data must be accompanied by data depicting the stability of residues under the conditions and for the time intervals specified.

7/ A crop group tolerance is not appropriate at the present time for the following reasons:

- o No data were submitted for radishes, a representative commodity of this group.
- o The established tolerances for commodities of this group differ by a factor of more than 5X, the tolerances on carrots and turnip roots are 0.05 ppm, and the tolerances on sugar beet roots and potato tubers are 0.5 ppm.
- o The registered uses for the representative commodities differ significantly, preharvest desiccation applications are permitted on potatoes but not in carrots or sugar beets or turnips; the maximum rate of treatment for the preplant/preemergence application on potatoes is 0.5 cation/A while on carrots and sugar beets it is 1 lb cation/A.

8/ Data are required depicting residues in granules, chips, and dried potatoes processed from tubers bearing measurable weathered residues. If residues are found to concentrate upon processing, appropriate food/feed additive regulations would be required; final disposition of food/feed additive regulations would be dependent upon the Agency's position regarding Delaney Clause issues.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

9/ Data are required depicting residues in or on sugar beet roots resulting from a preemergence application at 1 lb cation/A. Tests must be conducted in CA, ID, MN, ND.

10/ Data are required depicting residues in the processed products of sugar beets (dehydrated pulp, molasses, and sugar) from beets bearing measurable weathered residues. An exaggerated rate of application may be necessary to obtain measurable residues in the raw agricultural commodity. If residues are found to concentrate in the processed products, appropriate food/feed additive regulations would be required; final disposition of food/feed additive regulations would be dependent upon the Agency's position regarding Delaney Clause issues.

11/ A crop group tolerance is inappropriate at the present time for the following reasons:
- o The established tolerances for the representative commodities of this group differ by more than a factor of 5, the tolerance for sugar beet tops is 0.5 ppm, and the tolerance for turnip tops is 0.05 ppm.
- o Additional data are required to support existing tolerances for paraquat residues in or on sugar beet tops.

12/ Data are required depicting residues in or on sugar beet tops resulting from a preemergence application a 1 lb cation/A. Tests must be conducted in MN, CA, ID, and ND.

13/ Data are required depicting residues in or on turnip tops resulting from a preemergence application of the 2 lb/gal soluble concentrate (SC/L) formulation at 1 lb cation/A. Test must be conducted in AL or GA, AZ or CA, FL, TN, and TX.

14/ A group tolerance is not appropriate at the present time because data on representative commodities other than onions are not available.

15/ A group tolerance is not appropriate at the present time because data on representative commodities other than lettuce are not available.

16/ Adequate data are available for the representative commodities broccoli and cabbage. Adequate data are also available for collards, a commodity considered a suitable substitute for the representative commodity mustard greens. Since the registered usage on these crops is identical, a crop group tolerance of 0.05 ppm would be acceptable.

17/ A crop group tolerance is not appropriate at the present time for the following reasons:
- o There are no established tolerances for dry beans and peas, a tolerance is pending for dry beans.
- o The use directions differ significantly among commodities: preplant/preemergence applications are not permitted on greens, postemergence directed spray applications are permitted only on guar and soybeans, but the registered rate on guar is 2X the registered rate on soybeans.
- o Data in support of a proposed tolerance on pigeon peas are currently under review.

18/ The available data do not support the established 0.05 ppm tolerance for paraquat residues in or on soybeans following registered preharvest desiccation use of the paraquat formulations. Based on the submitted data it is recommended that the tolerance for paraquat residues be increased to 0.25 ppm.

19/ The available data demonstrate that residues may concentrate in the processed commodity hulls by a factor 11.2X, therefore, based on a recommended tolerance of 0.25 ppm, a food/feed additive regulation of 3.0 ppm is indicated for residues in hulls. Final disposition of this food/feed additive regulation is dependent upon the Agency's position regarding Delaney Clause issues.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

20/ A crop group tolerance is inappropriate at the present time for the following reasons:

- o Additional data are required to support existing tolerances for paraquat residues in or on bean hay, pea hay, and soybean forage.
- o Use directions differ significantly among commodities; postemergence directed spray and harvested aid applications are permitted only on soybeans.

21/ Data are sufficient to ascertain the adequacy of the estabished tolerance of residues of paraquat cation in or on bean forage, but not the established tolerances for residues in or on bean hay because no data were submitted concerning bean hay. The 40 CFR entry "bean forage" must be amended to "bean vines." The following data on bean hay are required.

- o Data depicting residues of paraquat cation in or on bean hay resulting from a single preemergence ground application of the 2 lb/gal SC/L formulation at 1 lb cation/A. Tests must be conducted in WI, NY, OR, and FL.

22/ The available data are adequate to support the established tolerance for residues of paraquat in or on pea forage. The 40 CFR entry of "pea forage" should be amended to the appropriate commodity definition "pea vines." No data were submitted concerning residues in or on pea hay. Thus, data must be submitted depicting residues in or on pea hay resulting from a single preemergence application of the 2 lb/gal SC/L formulations at 1 lb cation/A. Test must be conducted in WI, WA, and MN.

23/ The following data are required:

- o Data depicting residue in or on soybean forage and hay treated preemergence with the 2 lb/gal SC/L formulation at 1 lb cation/A. Tests must reflect both ground and aerial applications. Forage and hay must contain ~75% and 20% moisture, respectively, at the time of analysis. Tests must be conducted in IL, IA, IN, MO, MN, OH, and MS.
- o Data depicting residues of concern in or on soybean forage (harvested from both indeterminate and determinate varieties) collected on the day of and 5, 10, and 15 days following a preharvest desiccation with the 2 lb/gal SC/L formulation at 2 lb cation/A using ground and aerial equipment. Determinate varieties must be treated when soybeans are fully developed and indeterminate varieties must be treated when seed moisture is < 30%. Tests must be conducted in the major soybean production areas identified above.
- o Appropriate tolerances for paraquat residues in or on soybean hay and straw must be proposed and the existing tolerances for residues in or on soybean forage must be revised based on the above-requested data.

24/ The data are sufficient to support the established tolerance for residues in or on the members of the fruiting vegetables (except cucurbits) group.

25/ Data are required depicting residues in the commodities wet and dry pomace, puree, catsup, and juice processed from tomatoes bearing measurable weathered residues. If residues are found to concentrate in any of the processed commodities, appropriate food/feed additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

26/ Data are required depicting residues in or on the representative commodities of the cucurbit vegetables group; cucumbers melons (cantaloupe or muskmelon), and summer squash treated with 2 lb/gal SL/C formulation preplant at 1 lb cation/A; preemergence at 1 lb cation/A; and with multiple postemergence directed spray applications at 0.5 lb cation/A up to a day prior to harvest. Samples must be harvested 24 hours after the last postemergence directed spray application. Tests must be conducted in CA. Alternatively, the registrant may request cancellation of the SLN registration held by CA (CA-830054).

27/ The data are adequate to support the established tolerances for residues of paraquat in or on citrus fruits group. No additional data are required. However, the grazing restrictions must be expanded to prohibit the feeding of cover crops grown in treated areas to livestock.

28/ The data for apples and pears are adequate to support the established 0.05 ppm tolerances for residues of paraquat cation in or on these commodities. Since the registered uses for paraquat formulations on apples and pears are identical, the crop group tolerance of 0.05 ppm would be acceptable for all members of the pome fruits group provided that the grazing restriction for all pome fruits is expanded to prohibit the feeding of cover crops grown in treated areas to livestock.

29/ The data are adequate to support the established tolerances for paraquat on the representative commodities peaches, cherries, and plums. Since registered usage on these crops is identical, a crop group tolerance of 0.05 ppm would be acceptable provided the grazing restriction for all stone fruits is expanded to prohibit the feeding of cover crops grown in treated areas to livestock.

30/ Residue data must be submitted for dried prunes processed from fresh plums bearing measurable weathered residues. If residues are found to concentrate in dried prunes, an appropriate food additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

31/ The 40 CFR 180.205 entry "small fruit" is to be amended to read "small fruit (except strawberries and cranberries)." The specific use directions and limitations for cranberries should be established or cranberries should be specifically excluded from the tolerance (for residues in or on small fruit) and use directions. In the original petition, the use directions were different than for other berries.

32/ The grazing restriction for nuts must be expanded to prohibit the feeding to livestock of cover crops grown in treated areas.

33/ A group tolerance is not appropriate at the present time because additional data are required to support existing tolerances for paraquat residues in or on field corn and sweet corn (kernels plus cob with husks removed).

§158.125 Residue Chemistry - (cont'd)

34/ The following data are required to support the tolerances on field corn and sweet corn:

- Residue data for field corn grain harvested at normal maturity (~70-89% dry matter) following two postemergence, directed spray applications, the first in early July, and the second in August, with the 2 lb/gal SC/L formulation at 0.5 lb cation/A application. These data will satisfy requirements for postemergence use of paraquat for witchweed eradication and the postmergence use for control of annual broadleaf weeds and grasses. Tests must be conducted in IA, IL, NE, and OH.
- Residue data for sweet corn (kernels plus cob with husks removed) harvested 60 to 80 days after a single preemergence broadcast spray application with the 2 lb/gal SC/L formulation at 1 lb cation/A and, in separate tests, after a single postemergence, directed spray application with the SC/L at 0.5 lb cation/A. Tests must be conducted in CA (11%), FL (34%), NY, MN, WI, and OR or WA.

35/ An additional processing study is required in which field corn grain bearing detectable weathered residues of paraquat is processed into oil (crude and refined) and milled products. Exaggerated rates may be necessary to obtain detectable residues in or on grain. If residues are found to concentrate, a food/feed additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

36/ No data depicting residues in processed products were submitted, however, data requested for wheat milled products will be translated to oats.

37/ The available data for rice grain are currently under review, therefore, the adequacy of the proposed tolerance cannot be made at the present time.

38/ There are no data to assess the adequacy of the tolerance for paraquat residues in or on rye grains. A use for paraquat on rye and supporting data must be submitted. Alternatively, the tolerance for paraquat residues in or on rye grain will be deleted from the 40 CFR.

39/ An additional processing study is required in which grain sorghum bearing detectable, weathered residues resulting from presently registered uses of paraquat is processed into milled products and flour. Exaggerated rates may be necessary to obtain detectable residues in or on grain. If residues are found to concentrate, a food/feed additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

40/ The following data on wheat processed products are required:

- Wheat grain bearing measurable weathered residues of paraquat must be processed into milled products. Exaggerated rates may be necessary to obtain residues in or on grain. If residues are found to concentrate, a food/feed additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

41/ A crop group tolerance is not appropriate at the present time for the following reasons:
- o Additional residue data are required to support currently established tolerances for corn forage and fodder.
- o Data and tolerance proposals must be submitted for residues in or on barley hay and straw, corn silage, and hay and straw, sorghum silage and hay, and wheat hay and straw.

42/ No additional data are needed for barley hay and straw because the requested data for wheat hay and straw (when received) will be translated to barley.

43/ The following data are required:
- o Residue data for field corn forage, fodder, and silage treated preplant/preemergence with the 2 lb/gal SC/L formulation at 1 lb cation/A and postemergence by directed spray (once in July and once in August) with the same formulation at 0.5 lb cation/A/application. Samples must be collected on the day of final treatment and at regular intervals thereafter to determine the necessity of the PHI following postemergence directed spray treatments. Tests must be conducted in IA, MI, MN, NE, NY, or PA and WI. An approximate tolerance for paraquat residues in or on corn silage must be proposed and the existing tolerance on fodder and forage revised.
- o Residue data for sweet corn forage treated preplant/preemergence with the 2 lb/gal SC/L formulation at 1 lb cation/A. Tests must be conducted in CA, FL, and NE, MN, WI, and OR or WA.
- o The label directions for postemergence directed spray treatment of field corn must be modified by deleting the currently posted feeding and grazing restrictions.

44/ No additional data are needed for oat hay and straw because the requested data on wheat hay and straw (when received) will be translated to oats.

45/ A conclusion regarding the adequacy of the proposed tolerance cannot be made at the present time: the available data are currently under review.

46/ Data supporting the proposed preharvest aid use and tolerance for paraquat residues on sorghum fodder are currently under review and will not be assessed at this time. A tolerance of 0.05 ppm exists for paraquat residues in or on sorghum fodder. Tolerances for residues in or on silage and hay must be proposed based on the following required data:
- o Data reflecting residues in or on sorghum silage and hay harvested at normal maturity after a single preplant or preemergence application with the 2 lb/gal SC/L formulation at 1 lb cation/A and a postemergence directed spray treatment with the same formulation at 0.5 lb cation/A. Tests must be conducted in GA, KS, SD and NM, or TX.

47/ The following additional data are required:
- o Residues in or on wheat hay and straw harvested at normal maturity following a single preemergence broadcast spray application with the 2 lb/gal SC/L formulation at 1 lb cation/A. Tests must be conducted in KS, ND, and OK.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

48/ The following additional data are required:

- o Data depicting residues in or on forage and hay from pastures treated broadcast with the 2 lb/gal SC/L formulation at 0.5 lb cation/A. In areas east of the Rocky Mountains, tests conducted in TX, KY, NY, TN, AL and SD, and samples must be harvested 30 days posttreatment. In areas west of Cascade and Sierra Nevada Mountains, tests must be conducted in CA and OR or WA, and samples must be taken when growth has reached 3-6" height. A tolerance must be proposed for hay based on the results of the requested data, or a label restriction against the cutting treated grass must be proposed. (Note: The pending 60 ppm tolerance level may be acceptable.)
- o Data depicting residues in or on forage and hay from rangeland treated broadcast with 2 lb/gal SC/L formulation at 0.5 lb cation/A. Samples must be harvested the day of application. Tests must be conducted in the States cited above for areas west of the Rocky Mountains and areas west of the Sierra Nevada and Cascade Mountains. Tolerances must be proposed for grass forage and hay based on the requested studies.

49/ A crop group tolerance is inappropriate at the present time for the following reasons:

- o Additional data are needed for alfalfa and clover, the representative commodities of this group.

50/ The following additional data are needed:

- o Residues in or on alfalfa forage, seed and hay from pasture and rangeland treated broadcast with the 2 lb/gal SC/L formulation at 0.5 lb cation/A. Samples must be harvested the day of application. Tests must be conducted in the major alfalfa growing regions of the country, including WI, CA, NE, PA and NC.
  Tolerances must be proposed for alfalfa forage, seed and hay, based on the results of the requested studies. (Note: The pending 60 ppm tolerance level may be acceptable.)

51/ The following data are needed for alfalfa meal:

- o Residue data with meal processed from alfalfa bearing measurable weathered residues. If residues are found to concentrate in meal, an appropriate food/feed additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

52/ The following data are required:

- o Data depicting residues in or on birdsfoot trefoil from pasture and rangeland treated with the 2 lb/gal SC/L formulation at 0.5 lb cation/A. Samples must be harvested the day of application. Tests must be conducted in MI and WI. Tolerances must be proposed for forage and hay based on the results of the requested studies. (Note: The pending 60 ppm tolerance level may be acceptable.)

53/ The following data are required:

- o Data depicting residues in or on clover from rangeland treated with the 2 lb/gal SC/L formulation at 0.5 lb cation/A. Samples must be harvested the day of application. Tests must be conducted in TX (13%), MO (11%), KY, NY, and OR.
  Tolerances must be proposed for residues in or on clover forage and hay based on the required data. (Note: The pending 60 ppm tolerance level may be acceptable.)

54/ Since the tolerance for crown vetch is pending, no conclusions will be made at this time.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

55/ No further data are needed for avocados provided that the grazing restriction is expanded to prohibit the feeding of cover crops grown in treated areas to livestock.

56/ The following data are needed for processed coffee products:
- o Residues of concern must be determined in roasted beans and instant coffee from beans bearing measurable weathered residues. If residues concentrate in either of these processed products, an appropriate food additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

57/ Data are required depicting residues in or on cotton forage harvested 15 days after preharvest desiccation application of 2 lb/gal SC/L formulation at 0.5 lb cation/A. Tests must be conducted in AZ, CA, MS, and TX. Alternatively, a label restriction may be proposed against the foraging of livestock in treated areas.

58/ Based on available data a tolerance of 0.3 ppm must be proposed for figs or the following data are required:
- o Data reflecting paraquat residues on figs caught in ground nets or picked from trees after the last of several directed spray applications with the 2 lb/gal formulation at 1 lb cation/A application. Also, the label restriction against application when figs to be harvested are on the ground is required. The grazing restriction must be expanded to prohibit the feeding of cover crops grown in treated areas to livestock.

59/ The following data are needed on processed figs:
- o Data from processing studies reflecting residues of concern in or on dried figs must be submitted. Fresh figs used for drying must exhibit measurable weathered residues. If residues are found to concentrate following processing, an appropriate food additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

60/ The grazing restriction must be expanded to prohibit the feeding of cover crops grown in treated areas to livestock.

61/ The tolerance on hop vines will be revoked because hop vines are not a raw agricultural commodity of hops nor are they a feed item.

62/ The following data are needed on spent hops:
- o Residues of concern in or on spent hops harvested after the last of three directed spray applications with the 2 lb/gal SC/L formulation at 0.5 lb cation/A/application. If residues are found to concentrate upon processing, an appropriate food/feed additive regulation would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

63/ The data indicate that residues in dried hops processed from green hops may concentrate up to 5.3X. Therefore, the food additive regulation on dried hops should be increased from 0.2 ppm to 0.5 ppm. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

64/ An increased tolerance of 0.1 ppm must be proposed for olives. Alternatively, a label restriction prohibiting application when olives to be harvested are on the ground must be proposed.

65/ Residue data are needed for olive oil processed from olives bearing measurable residues (exaggerated rates may be necessary) demonstrating whether residues concentrate in olive oil. If residues are found to concentrate, an appropriate food additive regulation for olive oil would be required. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

66/ The available data will be adequate to support the established tolerance on pineapple provided a label restriction is added limiting the number of applications to three a season.

67/ A feed additive regulation for residues of paraquat cation in or on pineapple forage is indicated. Review of available data suggest that a tolerance of 0.05 ppm may be appropriate. However, final disposition of food/feed regulations is dependent upon the Agency's position regarding Delaney Clause issues.

68/ Residues must be determined in pineapple juice and bran processed from pineapple bearing measurable residues. If residues are found to concentrate in either of the processed products, an appropriate food/feed additive regulation would be required. However, final disposition of food/feed regulations is dependent upon the Agency's position regarding Delaney Clause issues.

69/ No further data will be required provided that the grazing restriction is expanded to prohibit the feeding of cover crops grown in treated areas to livestock.

70/ The following additional data are needed:

- o Data depicting paraquat residues in and on sugarcane forage from tests reflecting the following treatment schedule: 1) Two early season applications of the 2 lb/gal SC/L at rates of a least 0.5 ai/A, applied in 100 to 200 gallons of water per acre; 2) A single preharvest desiccation treatment of the 2 lb/gal SC/L at 0.25 ai/A applied by air in no more than 10 gal of water per acre. Cane and forage must be harvested no more than 3 days after desiccant application, and no more than 30 days following the final postemergence weed-control treatment. An adequate residue analytical method must be used in these studies. The test must be performed in FL and HI. Alternatively, a label restriction prohibiting the feeding or grazing of livestock on treated forage may be proposed rather than submitting forage residue data.

71/ Food additive regulations of 2.5 ppm in bagasse and 4 ppm in sugarcane juice are indicated. These levels are based on the results of processing studies submitted under the currently registered weed control and desiccant use of paraquat on sugarcane. However, final disposition of food/feed regulations is dependent upon the Agency's position regarding Delaney Clause issues.

72/ Residues must be determined in molasses and refined sugar processed from sugarcane bearing measurable residues. If residues are found to concentrate in either of these processed products, appropriate feed addit regulations would be required. However, final disposition of food/feed regulations is dependent upon the Agency's position regarding Delaney Clause issues.

73/ A food/feed additive tolerance of 10 ppm is indicated for residues in sunflower meal. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

74/ The established tolerances of 6 ppm in sunflower hulls should be increased to 15 ppm. However, final disposition of food/feed additive regulations is dependent upon the Agency's position regarding Delaney Clause issues.

75/ The following data are needed:

- o A validated analytical method capable of detecting residues in cattle liver at or below the established 0.01 ppm tolerance. EPA recommends that the registrant test the method used for pig liver, which has the required sensitivity.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.125 Residue Chemistry - (cont'd)

- o A feeding study depicting residues in liver of cattle fed paraquat cation at no less than 11.2 ppm in the diet over a 28-day period and killed within 24 hours after the feeding period. Residues must be determined by the validated method requested above.
- o As an alternative to the above, a proposed higher tolerance level in liver and kidney may be acceptable.

76/ A feeding study is required depicting residues in the fat, meat, and meat byproducts of poultry fed paraquat cation at no less than 1.4 ppm in the diet for 28 days and killed within 24 hours after the feeding period. Eggs must be collected and analyzed for residues of paraquat at intervals throughout the feeding period. A validated analytical method capable of detecting residues of paraquat cation at 0.01 ppm must be used.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[3]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A,B,G,H	Yes	00148506	No
Photodegradation					
161-2 - In Water	TGAI or PAIRA	A,B,G	No		Yes 9 Months
161-3 - On Soil	TGAI or PAIRA	A,G	Yes	00146806 00146807	No
161-4 - In Air	TGAI or PAIRA	A	No		No
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,G,H	No		Yes 27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes 27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	G	No		No[4]
162-4 - Aerobic Aquatic	TGAI or PAIRA	N/A[5]	N/A[5]		No
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,G,H	No		Yes 12 Months
163-2 - Volatility (Lab)	TEP	A	No		No
163-3 - Volatility (Field)	TEP	A	No		No

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1/]	Use Pattern[2/]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[3/]
§158.130 Environmental Fate - (cont'd)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B,H	No		Yes 27 Months
164-2 - Aquatic (Sediment)	TEP	None	N/A[5/]		No
164-3 - Forestry	TEP	G	No		No[4/]
164-4 - Combination and Tank Mixes		N/A[5/]	N/A[5/]		No
164-5 - Soil, Long-term	TEP	A	No		Conditional[6/] 50 Months
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes 39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Conditional[7/] 50 Months
165-3 - Irrigated Crops	TEP	N/A[5/]	N/A[5/]		No
165-4 - In Fish	TGAI or PAIRA	A,B,G	No		No
165-5 - In Aquatic Nontarget Organisms	TEP	G	No		Yes 12 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.130 Environmental Fate - (cont'd)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

4/ This study is not currently required based on preliminary data which indicate that paraquat leaching out of treated areas into soil would be almost totally absorbed and less than 1% desorption would subsequently occur, and provided there is no substantial increase in total poundage used or no major change in use pattern.

5/ N/A = Not applicable for the purposes of this Standard.

6/ Conditionally required; depends upon dissipation rate in the field dissipation study.

7/ Conditionally required--if significant residues of concern are found in the confined study. Consult with Agency upon completion of confined study.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[3]
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	N/A[4]			No
132-1 - Soil Dissipation	TEP	N/A[4]			No
133-3 - Dermal Exposure	TEP	N/A[4]			No
133-4 - Inhalation Exposure	TEP	N/A[4]			No
§158.142 Spray Drift					
201-1 - Droplet Size Spectrum	TEP	A,B	Yes	00153437 00153438	No
201-1 - Drift Field Evaluation	TEP	A,B	Yes	00153437 00153438	No

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[1] Composition: TEP = Typical end-use product.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

[3] Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

[4] N/A = Not applicable for the purpose of this Standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[3]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,H	Yes	00054573 00162748 00081825 00162870	No
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,H	Yes	00054574 00162748	No
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B,H	No		No[4]
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding: - Rodent, and	TGAI	A	No		No[5]
- Nonrodent (Dog)		A	Yes	00072416	No
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,H	Yes	00156313	No
82-3 - 90-Day Dermal - Rabbit	TGAI	A,B,H	No		No[6]
82-4 - 90-Day Inhalation: - Rat	TGAI	A,B,H	Partially	00030788 00113718	Yes[7] 15 Months
82-5 - 90-Day Neurotoxicity: - Hen	TGAI	A,B,H	No		No[6]
- Mammal		A,B,H	No		No[6]

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission3/
§158.135 Toxicology - (cont'd)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: - Rodent, and	TGAI	A,B	Yes	00138637	No
- Nonrodent (Dog)		A,B	Yes	00132474	No
83-2 - Oncogenicity - 2 species:	TGAI				
- Rat (preferred), and		A,B	Yes	00138637 40183501	No
- Mouse (preferred)		A,B	Yes	00087924	No
83-3 - Teratogenicity - 2 species:	TGAI				
- Rat		A,B,H	Yes	00113714	No
- Mouse		A,B,H	Yes	00096338	No
83-4 - Reproduction - Rat 2-generation	TGAI	A,B,H	Yes	00126783	No

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission3/
§158.135 Toxicology - (cont'd)					
MUTAGENICITY TESTING:					
84-2 - Gene Mutation	TGAI	A,B,H	Yes	00152690 00152691	No
84-2 - Structural Chromosomal Aberration	TGAI	A,B,H	Yes	00073487 00152692	No
84-4 - Other Genotoxic Effects	TGAI	A,B,H	Yes	00152693 00152695	No
SPECIAL TESTING:					
85-1 - General Metabolism	PAI or PAIRA	A,B,H	Yes	00028597 00036297 00028598 00055107 00028599 00126096	No
85-2 - Dermal Penetration	Choice	A,B,H	Yes	00126096 00126097 00126098 00126099	No
86-1 - Domestic Animal Safety	Choice	A,B,H	No		No

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.135 Toxicology - (cont'd)

1/ Composition: PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabeled; Choice - Choice of several test substances determined on a case-by-case basis.

2/ The use patterns are coded as follows: A - Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

4/ This study is not required because paraquat is not a carbamate or an organophosphate and is not chemically related to these compounds.

5/ The acceptable 2-year rat study fulfills this requirement.

6/ The registered use of the product does not involve purposeful application to human skin and its pesticidal use does not result in comparable human exposure.

7/ The submitted studies were classified as supplemental data because several important parameters were either not tested or were inadequately tested. Because of very low LC_{50} values and very low NOEL, a 90-day study with coarse particles (and with complete histopathology, organ weights, hematology, and clinical chemistry) should be performed.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition1/	Use Pattern2/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission3/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,G,H	Yes	00102038 05008363 00029001	No
71-2 - Avian Subacute Dietary Toxicity	TGAI	A,B,G,H			
- Upland Game Bird, and			Yes	00088881	No
- Waterfowl			Yes	00088881	No
71-3 - Wild Mammal Toxicity	TGAI	A,B,G,H	Yes	00162745	No
71-4 - Avian Reproduction	TGAI				
- Upland Game Bird, and		A	Yes	00110453 00110455 00110454 00162746	No
- Waterfowl		A	Yes	00110453 00110455 00110454 00162746	No
71-5 - Simulated Field Testing - Mammals, and	TEP	A	Yes	00162741 00162747	No
- Birds		A	Yes	00162741 00162747	No
- Actual Field Testing	TEP				
- Mammals, and		A	Yes	00162741 00162747	No
- Birds		A	Yes	00162741 00162747	No

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[3]
§158.145 Wildlife and Aquatic Organisms - (cont'd)					
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish Toxicity	TGAI				
- Cold-water Fish Species, and		A,B,G,H	Yes	00116622 00162737 00162736 00162738	No
- Warmwater Fish Species		A,B,G,H	Yes	00116622 00162738 00162737 GS0262-028	No
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,G,H	Yes	00114473 00116622 GS0262-028	No
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	A	No		No[4]
72-4 - Fish Early Life Stage, and	TGAI	A	No		No[5]
- Aquatic Invertebrates Life Cycle		A	No		No[5]

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission[3]/
§158.145 Wildlife and Aquatic Organisms - (cont'd)					
72-5 - Fish - Life Cycle	TGAI	A	No		No[5]/
72-6 - Aquatic Organism Accumulation	TGAI, PAI or Degradation Product	A			
- Crustacean			No		No
- Fish			No		No
- Insect Nymph			No		No
- Mollusk			No		No
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A	No		No[6]/
- Actual Field Testing - Aquatic Organisms		A	No		No[6]/

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

§158.145 Widlife and Aquatic Organisms - (cont'd)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; TEP = Typical end-use product;

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood Crop; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

4/ These studies are not required because paraquat binds tightly to sediment and is biologically unavailable, is only moderately toxic to aquatic organisms and has a low estimated environmental concentration.

5/ These studies are required for pesticides that may have continuous or recurrent exposure to fish. There are no aquatic uses for paraquat and paraquat is not likely to transport to water in significant quantities from runoff.

6/ These studies are required for pesticides intended for application to water or for pesticides that may translocate to aquatic habitat and will occur at potentially toxic levels; neither of these situations is likely to occur.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP		3/		
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI		3/		
122-1 - Vegetative Vigor	TGAI		3/		
122-2 - Aquatic Plant Growth	TGAI		3/		
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI		3/		
123-1 - Vegetative Vigor	TGAI		3/		
123-2 - Aquatic Plant Growth	TGAI		3/		
TIER III					
124-1 - Terrestrial Field	TEP		3/		
124-2 - Aquatic Field	TEP		3/		

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; EP = End-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood Crop; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ These data are not required in accordance with §158.150.

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]/	Use Pattern[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honeybee acute contact toxicity	TGAI	A,B	Yes	00028772 05001991	No
141-2 - Honeybee - toxicity of residues on foliage	TEP	A,B	No		No[3]/
141-4 - Honeybee subacute feeding study	(Reserved)[4]/				
141-5 - Field testing for pollinators	TEP	A,B	No		No[3]/

TABLE A
GENERIC DATA REQUIREMENTS FOR PARAQUAT DICHLORIDE

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission
§158.155 Nontarget Insect - (cont'd)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	(Reserved)[5]				
142-1 - Aquatic insect life-cycle study	(Reserved)[5]				
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)[5]				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)[5]				

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[1] Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Nonfood; C = Aquatic, Food Crop; D = Aquatic, Nonfood; E = Greenhouse, Food Crop; F = Greenhouse, Nonfood; G = Forestry; H = Domestic Outdoor; I = Indoor.

[3] As data from the acute study indicate low toxicity to honeybee, no further testing is required.

[4] Reserved, pending development of test methodology.

[5] Reserved, pending Agency discussion as to whether the data requirement should be established.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PARAQUAT DICHLORIDE

Guideline Citation and Name of Test	Test Substance1/	Guidelines Status1/	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Timeframe Listed Below2/
§158.120 Product Chemistry						
Product Identity						
61-1 - Product Identity and Disclosure of Ingredients	MP	R	☐	☒		No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	☒	☐	3,4	Yes 6 Months
61-3 - Discussion of Formation of Impurities	MP	R	☒	☐	5	Yes 6 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	CR	☒	☐	6	Yes 12 Months
62-2 - Certification of Limits	MP	R	☒	☐	7	Yes 12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	R	☒	☐	8	Yes 12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	R	☒	☐		Yes 6 Months
63-3 - Physical State	MP	R	☒	☐		Yes 6 Months
63-4 - Odor	MP	R	☒	☐		Yes 6 Months

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PARAQUAT DICHLORIDE

Guideline Citation and Name of Test	Test Substance[1]	Guidelines Status	Are Data Required Yes	Are Data Required No	Footnote Number	Data Must Be Submitted Within Timeframe Listed Below[2]
§158.120 Product Chemistry (cont'd)						
Physical and Chemical Characteristics (cont'd)						
63-7 - Density, Bulk, Density, or Specific Gravity	MP	R	☒	☐		6 Months
63-12 - pH	MP	CR	☒	☐		6 Months
63-14 - Oxidizing or Reducing Action	MP	CR	☒	☐		6 Months
63-15 - Flammability	MP	CR	☒	☐		6 Months
63-16 - Explodability	MP	R	☒	☐		6 Months
63-17 - Storage Stability	MP	R	☒	☐		15 Months
63-18 - Viscosity	MP	CR	☒	☐		6 Months
63-19 - Miscibility	MP	CR	☒	☐		6 Months
63-20 - Corrosion Characteristics	MP	R	☒	☐		15 Months
Other Requirements						
64-1 - Submittal of samples	MP	CR	☐	☒		

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[1] MP = Manufacturing-use Product; R = Required; CR = Conditionally Required

[2] Data must be submitted within the indicated timeframe, based on the date of the Guidance Document.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PARAQUAT DICHLORIDE

§158.120 Product Chemistry - (cont'd)

3/ Details of the manufacturing process including the relative amounts of beginning material; a description of the equipment used to produce the product, reaction conditions, the duration of the process; purification procedures, and quality control measures are required.

4/ The name and address of the manufacturer, producer, and supplier of each beginning material used to manufacture the product are needed. Also, a copy of all available technical specifications, data sheets, and other documents in which the manufacturer, producer, or supplier of the beginning materials describes its composition and properties must be submitted.

5/ The following data are required for the MUP's:
- o A discussion of each impurity believed to be present at ≥ 0.1% based on the knowledge of beginning materials, possible chemical reactions, and any contamination present.

6/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity present at ≥ 0.1% (w/w) using valid analytical methods.

7/ The following additional data are required:
- o Upper and lower limits must be provided, validated, and certified for each intentionally added inert in the MUP.
- o Upper limits must be provided, validated, and certified for each impurity present at ≥ 0.1% (w/w).
- o Upper and lower limits must be provided, validated, and certified for paraquat dichloride in the MUP.

8/ None of the methods for quantification of paraquat dichloride and manufacturing impurities in paraquat dichloride have been validated. Therefore, the following additional information is required:
- o Quantitiative methods are required to determine paraquat and all impurities and intentionally added inerts for which a certified limit is required. Each method must be accompanied by validation studies of the precision and accuracy of this method.

TABLE B
PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING PARAQUAT DICHLORIDE

Data Requirements	Composition	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA §3(c)(2)(B)? Timeframe for Data Submission
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Acute Oral Toxicity - Rat	MP	Yes	00054573 00081825 00162748 00162870	No
81-2 - Acute Dermal Toxicity - Rabbit	MP	Yes	00054574 00162748	No
81-3 - Acute Inhalation Toxicity - Rat	MP	Yes	00046105 00153733	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00054575	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00054576	No
81-6 - Dermal Sensitization Guinea Pig	MP	Yes	00155289 00162744	No

APPENDIX II

LABELING

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . . ," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ****" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD$_{50}$ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC$_{50}$ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD$_{50}$ of 100 mg/kg or less, or a subacute dietary LC$_{50}$ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) *Directions for Use*--(1) *General requirements*--(i) *Adequacy and clarity of directions*. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use*. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement:

> "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

APPENDIX III

USE INDEX

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PARAQUAT DICHLORIDE*

TYPE PESTICIDE: Herbicide, Defoliant, Desiccant, Plant Regulator

FORMULATIONS:
FI (29.1%, 43.5%)
SC/L (2 lb/gal, 20.4%)
PrL (0.276%)

GENERAL WARNINGS AND LIMITATIONS: RESTRICTED USE PESTICIDE. A nonselective herbicide and desiccant with fast acting contact action. Chemical is inactivated upon contact with soil. This chemical is toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes) or contaminate water by cleaning of equipment or disposal of wastes. Do not inhale spray mist. Remove and wash contaminated clothing. Wear full face shield, rubber gloves, apron and waterproof footwear when handling or mixing concentrate. Wear waterproof footwear and clothing when spraying or when contacting vegetation wet with spray. Do not enter treated areas without protective clothing until sprays have dried. Avoid working in spray mist. If there is risk of exposure wear goggles and approved face mask capable of filtering spray droplets. Keep all unprotected persons out of operating areas or vicinity where there may be danger of drift. Certain states may require more restrictive reentry intervals; consult your State Department of Agriculture. Written or oral warnings regarding use of protective clothing and accidental exposure must be given to workers who are expected to be in treated areas or in areas about to be treated. Apply when weeds are succulent and new growth is 1 to 6 inches high. Thoroughly cover weed foliage. Weeds emerging after application will not be controlled. Do not combine with suspension type fertilizers. For band treatments, reduce dosage proportionately.
Dosages for this chemical were calculated using the cation by weight.

Agricultural Crop Tolerances (other than those listed in text):

Beans, forage	0.1 ppm
Beans, hay	0.4 ppm
Oat, grain	0.05 ppm
Rye grain	0.05 ppm

Livestock Tolerances:

Cattle (fat)	0.01 ppm	(N)
Cattle (meat)	0.01 ppm	(N)
Cattle (mbyp)	0.01 ppm	(N)
Eggs	0.01 ppm	(N)
Goats (fat)	0.01 ppm	(N)
Goats (meat)	0.01 ppm	(N)
Goats (mbyp)	0.01 ppm	(N)
Hogs (fat)	0.01 ppm	(N)
Hogs (meat)	0.01 ppm	(N)
Hogs (mbyp)	0.01 ppm	(N)

*1,1'-dimethyl-4,4'-bipyridinium dichloride

GENERAL WARNINGS AND LIMITATIONS (continued)

Milk	0.01 ppm (N)
Poultry (fat)	0.01 ppm (N)
Poultry (meat)	0.01 ppm (N)
Poultry (mbyp)	0.01 ppm (N)
Sheep (fat)	0.01 ppm (N)
Sheep (meat)	0.01 ppm (N)
Sheep (mbyp)	0.01 ppm (N)

TIME REQUIRED FOR CONTROL: Acts within a few hours of application.

PHYTOTOXICITY TO TARGET WEEDS: Causes wilting and rapid desiccation of foliage.

PHYTOTOXICITY TO CROPS: Plants emerged at the time of application will be killed.

MODE OF ACTION: Causes the formation of free radicals during photosynthesis which acts to disrupt membrane permeability.

BROADLEAF WEEDS CONTROLLED:

PAAAAAB	Annual broadleaf weeds	
PCQBIAA	Burclover	
PBFAEAC	Bursage	
PEHAGAA	Buttercup	
PBZACBA	Carolina geranium	
PAZAAAC	Chickweed	
PCQAAAB	Clover	
PBFDQAA	Cocklebur	(a)
PBFAEBA	Common ragweed	
PEWAHBL	Cutleaf groundcherry	
PBFDHBB	Dandelion	
PEDABBA	Desert rockpurslane	
PEAAHAA	Dock	
PBFBIBB	Dogfennel	
PARABAA	Fiddleneck	(b)
PBZABAA	Filaree	
PEMAEBB	Florida pursley	
PBFCXAA	Groundsel	
PCOAFBA	Henbit	
PBDAEAB	Lambsquarter	
PBGAAAB	Morningglory	(c)
PFGAEAA	Nettle	
PAAAAAF	Perennial weeds	(c)
PAAAABI	Pigweed	(b)
PDXABAA	Plantain	
PBFCEBF	Prickly lettuce	
PFMAFBB	Puncturevine	
PAAAABP	Purslane	
PBFAEAA	Ragweed	

PARAQUAT DICHLORIDE

BROADLEAF WEEDS CONTROLLED (continued)

PCQBYBH	Red clover	
PBKAHBA	Shepherdspurse	(c)
PCQAMBF	Sicklepod	
PZAAACS	Smartweed	
PBFDUAA	Spikeweed	(b)
PBVAGAA	Spurge	
PBKANBB	Tansy mustard	
PAAAAAX	Thistle	
PBKBDBA	Tumble mustard	
PDAABBB	Velvetleaf	
PBKAFBE	Wild mustard	
PBKBABA	Wild radish	
PEUANBA	Witchweed	
PDPABAA	Woodsorrel	

(a) Use the higher dosages.
(b) Treat when weeds are small.
(c) Top kill and suppression only.

GRASSES AND OTHER MONOCOTS CONTROLLED:

PCACKBA	Annual bluegrass	
PCAAAAB	Annual grasses	
PCABSAA	Barley (volunteer)	
PCABHBB	Barnyardgrass	
PCAAZBA	Bermudagrass	(c)
PCACKAA	Bluegrass	
PCAARBD	Broadleaf signalgrass	
PCAATAA	Brome	(a)
PCACFBL	Bull paspalum	
PCAATBK	Cheat	
PCABRBA	Common velvetgrass	
PCABFAA	Crabgrass	(b)
PCAATBM	Downy brome	
PCACEBD	Fall panicum	
PCAAFAA	Foxtail	
PCACUBA	Giant foxtail	
PCABIBA	Goosegrass	
PCAAAAA	Grasses	
PCABZBA	Italian ryegrass	
PCACWBC	Johnsongrass	(c)
PCACWBG	Johnsongrass (seedling)	
PCABSBF	Little barley	(d)
PCACBBD	Nimblewill	
PBMADAA	Nutsedge	
PCABBBA	Orchardgrass	
PCAAAAC	Perennial grasses	(c)
PCACCBA	Rice	
PCABZAA	Ryegrass	
PCAARAA	Signalgrass	
PCAATBE	Smooth brome	(c)

GRASSES AND OTHER MONOCOTS CONTROLLED (continued)

PCABMBE	Tall fescue	
PCACEBL	Texas panicum	
PCACIBA	Timothy	(c)
PCAAOBB	Wild oats	

(a) Use the higher dosages.
(b) Treat when weeds are small.
(c) Top kill and suppression only.
(d) Apply at mid-boot stage.

WOODY PLANTS CONTROLLED:

PAHABBI	Poison ivy	
PAAAAAI	Trees	
PAAAAAD	Woody plants	(c)

(c) Top kill and suppression only.

PLANT REGULATOR CLAIMS:

PZZZZZC	Defoliant
PZZZZZB	Desiccant
PZZZZZA	Plant regulator (resin soaking)

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations

TERRESTRIAL FOOD CROP

(Agricultural Crops)

General Warnings and Limitations: Do not use around home gardens, schools, recreational parks or playgrounds. To prevent injury to germinating crop seedlings, do not apply preplant or preemergence to soils lacking clay minerals, i.e., peat, mulch, pure sand or artificial planting media. For band or spot treatment, reduce dosage in proportion to area actually treated. Apply a surfactant.

/06020AA	Acerola	0.05 (N) ppm (acerola, apricot, avocado, banana, cherry, citrus fruits, coffee beans, fig, nectarine, nuts, olive, papaya, plums (fresh prunes)) Do not graze treated areas. Do not feed cover crops grown in treated areas to livestock. General Information: Do not apply when nuts or figs to be harvested are on the ground.
/05001AA	Apricot	
/28000AA	Avocado	
/06002AA	Banana	
/05002AA	Cherry	
/20001AA	Citrus Fruits	
/01002AA	Coffee	
/06005AA	Fig	
/03005AA	Filbert	
/03007AA	Macadamia Nut	
/05003AA	Nectarine	
/28014AA	Olive	
/06010AA	Papaya	
/05005AA	Plum (fresh prunes)	
/05006AA	Prune	
	0.50-1.00 (2 lb/gal SC/L)	Directed spray. Apply in 30 to 150 gallons of water per acre. Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees. Retreatment or spot treatment may be necessary for hard-to-kill weeds.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/23001AA	Alfalfa	5 ppm 42 day preharvest interval. 5 day postharvest interval.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.
	0.12-0.50 (2 lb/gal SC/L)	Use limited to CA. Postemergence. Broadcast. For suppression and control of weeds in alfalfa seedlings grown for hay. Apply in 25 to 50 gallons of water per acre in late winter or early spring. Use the lower dosage rate for alfalfa with 3 trifoliate leaves, a median dosage rate when alfalfa has 6 trifoliate leaves, and the higher dosage when there are 9 or more leaves. Alfalfa foliage will be burned. Do not apply more than once during the first growing season. Seedling alfalfa stands will be reduced and replanting may be necessary.
	0.25-0.75 (2 lb/gal SC/L)	Postemergence. Broadcast. Tank mix with simazine. Apply in 20 to 100 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Do not apply more than once per season.
	0.50-0.75 (2 lb/gal SC/L)	Use limited to CA (counties of Del Norte, Siskiyou, Modoc, Shasta, Lassen, Plumas, Sierra and Nevada), CO, ID, MT, NV, OR, UT, WA, and WY. Dormant application. Broadcast. Apply in 20 to 100 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Do not apply if regrowth, following the last fall cutting, is more than 2 inches tall. Crop foliage will be burned. Do not apply more than once per season.

PARAQUAT DICHLORIDE

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Alfalfa (continued)	
	0.5-0.75 (2 lb/gal SC/L)	Use limited to states east of the Rockies and north of the southern borders of CO, KS, KY, MS, VA. Dormant application. Broadcast. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air.
	[SLN] 0.25 (2 lb/gal SC/L)	SLN - Use limited to AL. Postharvest. Broadcast to established stands at least one year old. Apply in 20 to 60 gallons of water per acre by ground immediately after alfalfa has been removed for silage or hay. A non-ionic surfactant may be applied to the finished spray.
/03001AA	Almond	0.05 (N) ppm (almond) 0.5 ppm (almond hulls) Do not graze treated areas. General Information: Do not apply when nuts to be harvested are on the ground. Do not treat Mission variety of almonds.
	0.50-1.00 (2 lb/gal SC/L)	Use limited to CA. Directed spray. Apply in 30 to 150 gallons of water per acre. Retreatment or spot treatment may be necessary for hard-to-kill weeds.
/04001AA /04003AA	Apple Pear	0.05 (N) ppm Do not graze treated areas. General Information: Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees. Make only 1 application per year. Apply only in orchards where trees have been established 1 year or more.
	0.50-1.00 (2 lb/gal SC/L)	Directed spray. Apply in 30 to 150 gallons of water per acre. Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees. Retreatment or spot treatment may be necessary for hard-to-kill weeds.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Apple cluster (continued)	
	0.50-1.00 (2 lb/gal SC/L)	Use limited to MI. Directed spray. Tank mix with simazine. Apply 50 to 130 gallons of water per acre. Use the lower dosage on coarse textured or low organic matter soils, and the higher dosage on fine textured or high organic matter soils. Do not apply to sandy soil.
	Apricot	See Acerola cluster.
/16002AA	Asparagus	0.5 ppm 6 day preharvest interval.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 50 to 100 gallons of spray per acre. Seeding or transplanting should be done with a minimum of soil disturbance. Allow maximum weed emergence prior to treatment. For plantings established 2 years or more, tank mix with simazine.
	Avocado	See Acerola cluster.
/22025AA	Bahiagrass (pasture, rangeland)	5 ppm Do not graze treated areas within 60 days after treatment.
	0.25 (2 lb/gal SC/L)	Use limited to the South and Southeast. Broadcast or band. Use band treatment over the drill row when recovery of sod is desired. Apply in 20 to 30 gallons of water per acre in late summer or early fall, prior to or at time of seeding winter annuals. Apply broadcast when existing grass species are undesirable and total suppression is required. Sod must not exceed 3 inches in height.
	Banana	See Acerola cluster.

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PARAQUAT DICHLORIDE

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/28063AA	Barley	0.05 (N) ppm (grain) Do not graze treated areas or feed treated grain to livestock.
	0.25-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.
/15002AA	Beans (lima)	0.05 ppm (beans (lima, succulent), broccoli, cantaloupe, cabbage, carrots, cauliflower, chinese cabbage, collards, cucumber, muskmelon, peas (succulent), pumpkin, squash, watermelon) 0.2 ppm (peas, forage) 0.8 ppm (peas, hay) 0.05 ppm (turnips, roots, tips) General Information: Seeding should be done with a minimum of soil disturbance. Crop plants emerged at time of application will be killed. Add a non-ionic surfactant.
/13005AA	Broccoli	
/13007AA	Cabbage	
/1002AA	Cantaloupe	
/14003AA	Carrots	
/13008AA	Cauliflower	
/13010AA	Chinese Cabbage	
/13009AA	Collards	
/10010AA	Cucumber	
/11001AA	Eggplant	
/1006AA	Muskmelon	
/15009AA	Peas	
/10011AA	Pumpkin	
/10012AA	Squash	
/13026AA	Turnips	
/10008AA	Watermelon	
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Use sufficient water to give thorough coverage. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence.
/22017AA	Bermudagrass (pasture, rangeland)	5 ppm Do not graze treated areas or mow for hay within 40 days after treatment.
	0.25 (2 lb/gal SC/L)	Use limited to the South and Southeast. Broadcast or band. Use band treatment over the drill row when recovery of sod is desired. Apply in 20 to 30 gallons of water per acre in late summer or early fall, prior to or at the time of seeding winter annuals. Apply broadcast when existing grass species are undesirable and total suppression is required. Sod must not exceed 3 inches in height.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Bermudagrass (pasture, rangeland) (continued)	
	0.25 (2 lb/gal SC/L)	Dormant application. Broadcast. For control of brome, buttercup, carolina geranium, little barley. Apply in 20 to 30 gallons of water per acre by ground or 3 to 5 gallons by air.
/01002AA /01009AA /01003AA /01006AA	Blackberry Blueberry Boysenberry Raspberry	0.05 (N) ppm (small fruits)
	0.50-1.00 (2 lb/gal SC/L)	Directed spray. Apply in 50 to 200 gallons of water per acre. Thoroughly wet weeds. Apply before emergence of new canes or shoots, as injury may result.
	Blueberry	See Blackberry cluster.
	Boysenberry	See Blackberry cluster.
	Broccoli	See Beans (lima) cluster.
	Cabbage	See Beans (lima) cluster.
	Cantaloupe	See Beans (lima) cluster.
	Carrots	See Beans (lima) cluster.
	Cauliflower	See Beans (lima) cluster.
	Cherry	See Acerola cluster.
	Chinese Cabbage	See Beans (lima) cluster.
	Citrus Fruits	See Acerola cluster.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/23003AA	Clover	5 ppm 42 day preharvest interval. General Information: Do not apply if regrowth, following the last fall cutting, is more than 2 inches tall. Do not apply more than once per season.
	0.50-0.75 (2 lb/gal SC/L)	Use limited to CA (counties of Del Norte, Siskiyou, Modoc, Shasta, Lassen, Plumas, Sierra and Nevada), CO, ID, MT, NV, OR, UT, WA, and WY. Dormant application. Broadcast. Apply in 20 to 100 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air.
	Coffee	See Acerola cluster.
	Collards	See Beans (lima) cluster.
/28005AA	Corn	0.05 (N) ppm (fresh (including sweet (K+CWHR)) 0.05 (N) ppm (sweet, grain, forage, and fodder) Do not graze treated areas.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.
	0.25-0.50 (2 lb/gal SC/L)	Preplant or preemergence. For use where corn will be planted directly into cover crop, established sod, or in previous crop residues. Tank mix with atrazine; atrazine plus simazine; bladex; or alachlor plus atrazine. Apply in 20 to 60 gallons of water per acre. Tank mix of paraquat dichloride and atrazine may be applied in liquid nitrogen fertilizer and/or complete liquid fertilizer solutions in combination with a non-ionic surfactant.
	0.25-0.50 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast. Tank mix with metolachlor and atrazine.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Corn (continued)	
	0.50 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast. Tank mix with metolachlor and cyanazine.
	0.25-0.50 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast. Tank mix with metolachlor and metribuzin or linuron.
	0.50 (2 lb/gal SC/L)	Postemergence. Directed spray. For use in United States Department of Agriculture Witchweed Eradication Program. Apply in 10 to 20 gallons of water per acre. Initiate treatment in early July and repeat in early August if regrowth of grass weeds occurs.
/28006AA	Corn, Field	0.05 (N) ppm (grain, fodder, and forage)
	0.25 (2 lb/gal SC/L)	Postemergence. Directed spray. Apply in 20 to 40 gallons of water per acre. For control of weeds and grasses less than 4 inches tall. Apply when corn plants are at least 10 inches tall. Direct spray no higher than the lower 3 inches of corn stalks. Do not mix with liquid fertilizer. May be tank mixed with atrazine.
'28007AA	Cotton	0.5 ppm (cottonseed) 3 day preharvest interval. Seven day preharvest interval when used with phosphate or chlorate defoliants. Do not graze lactating dairy animals. Do not graze livestock in treated fields until 15 days after treatment. Remove livestock from treated area 30 days before slaughter. Do not feed gin trash to livestock. General Information: May be applied as a split application. Repeat application if necessary. Do not make more than 2 applications or exceed a total of 2 pints per acre.
	0.12-0.25 (2 lb/gal SC/L)	Use limited to CA. For control of emerged volunteer barley. Preplant. Broadcast. Apply in 5 to 10 gallons of water per acre by air. Apply to preformed seedbeds.

Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
Cotton (continued)	
0.50-1.00 (2 lb/gal SC/L)	Preplant. Broadcast. Apply in 20 to 60 gallons of water per acre. Beds should be preformed to permit maximum weed emergence prior to treatment. Seeding should be done with a minimum amount of soil disturbance.
0.12 (2 lb/gal SC/L)	Preharvest desiccation. Broadcast. Tank mix with phosphate or chlorate defoliants. Apply in 10 to 30 gallons of water per acre by ground or 3 to 10 gallons by air. Apply when 80 percent or more of the bolls are open and the remaining bolls are mature.
0.25-0.50 (2 lb/gal SC/L)	Preharvest desiccation of stripper cotton. Broadcast. Apply in 10 to 30 gallons of water per acre by ground or 3 to 10 gallons by air when 85 percent or more of the bolls are open and the remaining bolls are mature. When foliage is dense, use 2 applications of the lower dosage if necessary.
0.12 (2 lb/gal SC/L)	Use limited to AZ and CA. Preharvest defoliation. Broadcast. Tank mix with phosphate or chlorate defoliants. Apply in 10 to 30 gallons of water per acre by ground or 3 to 10 gallons by air when 60 percent or more of the bolls are open and the remaining bolls are mature.
Cucumber	See Beans (lima) cluster.
Eggplant	See Beans (lima) cluster.
Fig	See Acerola cluster.
Filbert	See Acerola cluster.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/01014AA	Grapes	Do not graze treated areas. Do not use in vineyards established less than 3 years.
	0.50-1.00 (2 lb/gal SC/L)	Use limited to CA. Directed spray. Postemergence. Apply in 50 to 150 gallons of water per acre. Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around vines. Retreatment or spot treatment may be necessary for hard-to-kill weeds.
/28066BA	Grasses (grown for seed)	5.0 ppm grass, pasture, rangeland Do not graze treated areas. Do not use seed from treated areas for animal feed. Do not use straw from treated areas for animal bedding or feed.
	0.50 (2 lb/gal SC/L)	Preplant. Broadcast. Apply in 20 to 40 gallons of water per acre to seedbed when weeds are at the 3 to 5 leaf stage. Treatment can be repeated prior to or on the day of seeding. Add a non-ionic surfactant to the finished spray.
/26011AA	Guar	0.5 ppm (guar beans) 4 day preharvest interval. Do not graze treated areas or feed treated forage to livestock.
	0.50 (2 lb/gal SC/L)	Preharvest desiccation. Broadcast. Apply in 20 to 30 gallons of water per acre after pods are mature.
/06006AA /06014AA	Guava	0.05 (N) ppm Do not graze treated areas. Do not feed cover crops grown in treated areas to livestock.
	1.00 (2 lb/gal SC/L)	Preemergence. Directed spray. Apply in 50 to 150 gallons of water per acre. Do not allow spray to contact green stems, fruit or foliage, as injury may result. Use a shield when applying around young trees. Retreatment or spot treatment may be necessary for hard-to-kill weeds.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/08020AA	Hops	0.1 ppm (fresh hops) 0.5 ppm (hop vines) 14 day preharvest interval. Do not allow animals to graze in treated hopyards. Hop vine refuse and silage may be fed to livestock. General Information: Do not apply more than 3 times per season. Do not allow spray to contact green stems, foliage, flowers, or cones, as injury may result.
	0.50 (2 lb/gal SC/L)	Use limited to ID, OR, and WA. Directed spray. Postemergence. Apply in 20 to 100 gallons of water per acre. Spray in interspaces and around the base of hop plantings. Do not apply around hop vines less than 10 feet tall. Retreatment or spot treatment may be necessary.
	(Cascade, Yakima Cluster and Bullion varieties)	
	0.50 (2 lb/gal SC/L)	Postemergence. Directed spray. Apply in 20 to 100 gallons of water per acre. For suckering and stripping, spray only basal 2 feet of vines. Do not apply to hop vines less than 10 feet tall. Repeat as necessary.
/06018AA /03011AA	Kiwi Fruit	0.05 ppm Do not treat more than 3 times per year. 14 day preharvest interval. General Information: Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying young trees.
	0.50-1.00 (2 lb/gal SC/L)	Directed spray. Apply in 30 to 150 gallons of water per acre. Retreatment or spot treatment may be necessary for hard-to-kill weeds.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/13020AA	Lettuce	0.05 (N) ppm
	0.12-0.25 (2 lb/gal SC/L)	Use limited to CA. For control of emerged volunteer barley. Preplant. Broadcast. Apply in 5 to 10 gallons of water per acre by air to preformed seedbeds
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.
	Macadamia Nut	See Acerola cluster.
/10001AA	Melons	0.05 ppm
	0.12-0.25 (2 lb/gal SC/L)	Use limited to CA. For control of emerged volunteer barley. Preplant. Broadcast. Apply in 5 to 10 gallons of water per acre by air to preformed seedbeds.
	0.50-1.00 (2 lb/gal SC/L)	Preplant and preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.
	Muskmelon	See Beans (lima) cluster.
	Nectarine	See Acerola cluster.
	Olive	See Acerola cluster.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/14011AA	Onions	0.05 ppm (dry, bulb, green onions) 200 day preharvest interval in CA. 60 day preharvest interval elsewhere.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast to seeded onions. Apply in 20 to 100 gallons of water per acre. Allow maximum weed emergence prior to treatment. Use the higher dosage for heavy weed infestation and for control of wild oats. Seeding should be done with a minimum of soil disturbance.
	Papaya	See Acerola cluster.
/06014AA	Passion Fruit	0.2 ppm Do not graze treated areas. General Information: If bark is still green, wrap vine prior to application to prevent injury. If applied during harvest, apply only after picking fruit off the ground. Refer to Guava for dose and use patterns.
/28035AA	Pastures	5 ppm (grass, pasture, rangeland) General Information: Use band treatment when recovery of sprayed sod is desired. Broadcast when existing grass species are undesirable and total suppression is needed.
	0.25-0.50 (2 lb/gal SC/L)	Broadcast or band. Apply in sufficient water to make 17 to 75 gallons of dilute spray per acre. Use as a broadcast treatment when existing grass should be suppressed and as a band treatment when recovery of existing grass is desired.
	0.25-0.50 (2 lb/gal SC/L)	Use limited to east of Rocky Mountains. Broadcast or band. Apply prior to or at time of seeding grasses or forage legumes such as alfalfa, clover and birdsfoot trefoil. Use the higher rate to suppress vigorous and coarse sod species such as brome. Apply only to pastures which are not more than 2 to 3 inches in height.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Pastures (continued)	
	0.25-0.50 (2 lb/gal SC/L)	Use limited to west of Cascade and Sierra Nevada Mountains. Broadcast or band. Apply prior to or at time of seeding grasses such as hardinggrass and palestine orchardgrass. Apply in October through December after first fall rains and after weeds have emerged. Apply on moderate to heavily grazed areas. Do not use in areas with heavy sod and weed growth.
/05004AA	Peach	0.05 (N) ppm Do not graze treated areas. Do not treat trees established less than 3 years. Do not replant in treated soil. General Information: Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees. Make only 1 application per year. Apply only in orchards where trees have been established 1 year or more.
	0.50-1.00 (2 lb/gal SC/L)	Use limited to CA. Postemergence. Directed spray. Apply in 30 to 150 gallons of water per acre. Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees. Retreatment or spot treatment may be necessary for hard-to-kill weeds.
	0.50-1.00 (2 lb/gal SC/L)	Use limited to AR, LA, MO, OK, TX, and states East of the Mississippi River. Directed spray. Postemergence. Tank mix with simazine. Apply in 50 to 200 gallons of water per acre. Use the lower dosage on coarse textured or low organic matter soils, and the higher dosage on fine textured or high organic matter soils.
	Pear	See Apple cluster.
	Peas	See Beans (lima) cluster.

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PARAQUAT DICHLORIDE

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/03008AA	Pecan	0.05 (N) ppm (nuts) Do not graze treated areas. General Information: Do not apply when nuts to be harvested are on the ground.
	0.50-1.00 (2 lb/gal SC/L)	Postemergence. Directed spray. Apply in 30 to 50 gallons of water per acre. Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees. Retreatment or spot treatment may be necessary for hard-to-kill weeds.
/28017AA	Pepper	0.05 ppm (vegetables, fruiting) Do not graze treated areas.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.
	0.50 (2 lb/gal SC/L)	Use limited to Middle Atlantic, Southeast, South Central regions, and Southwest to the Western boundary of TX. Postemergence. Directed spray. Band application between the rows. Apply in 20 to 100 gallons of water per acre. Use shields to protect crop plants. Can be used between plastic mulch covered rows. Do not make more than 3 applications per crop season.
/08027AA	Peppermint Spearmint	0.5 ppm (mint, hay) 3.0 ppm (mint, hay, spent) Do not apply more than 3 pints of product per dormant season.
	0.38-0.75 (2 lb/gal SC/L)	Dormant application. Broadcast. Apply in 25 to 65 gallons of water per acre. May be tank mixed with terbacil.

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	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/06013AA	Pineapple	0.05 (N) ppm 20 day preharvest interval.
	0.50-1.00 (2 lb/gal SC/L)	Directed spray. Postemergence. Apply in 100 to 200 gallons of water per acre. Retreatment may be necessary on more mature weeds.
/03011AA	Pistachio	0.05 ppm 0.05 (N) ppm (nuts) Do not exceed 2 applications after shell split. 7 day preharvest interval. Do not graze treated areas or feed cover crops grown in treated areas to livestock.
		Refer to Kiwi Fruit for dose and use information.
	Plum (fresh prunes)	See Acerola cluster.
/14013AA	Potato	0.5 ppm 3 day preharvest interval. Do not graze livestock in treated potato fields. General Information: To avoid injury to subsequent crops, do not use on mulch or peat soils. Do not use for desiccating potato vines when potatoes are to be stored or used for seed. Add a non-ionic surfactant to the finished spray.
	0.12-0.25 (2 lb/gal SC/L)	Use limited to CA. For control of emerged volunteer barley. Preplant. Broadcast. Apply in 5 to 10 gallons of water per acre by air to preformed seedbeds.
	0.25-0.50 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast. Apply in 30 to 100 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Delay application to provide maximum weed emergence but not later than ground cracking.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Potato (continued)	
	0.25-0.50 (2 lb/gal SC/L)	Preharvest desiccation. Broadcast. Apply in 50 to 100 gallons of water per acre. Use the higher dosage where vine growth is vigorous or where quick vine kill is desired. Use 2 applications of the lower dosage when growth is dense. Use the lower rate on maturing vines. Do not make more than 2 applications with a minimum of 5 days between applications.
	Prune	See Acerola cluster.
	Pumpkin	See Beans (lima) cluster.
/28045AA	Rangeland	5 ppm (grass, pasture, rangeland) General Information: Use band treatment when recovery of sprayed sod is desired. Broadcast when existing grass species are undesirable and total suppression is needed. Apply with a non-ionic surfactant in 18 to 75 gallons of water per acre.
	0.25-0.50 (2 lb/gal SC/L)	Broadcast or band. Apply in sufficient water to make 17 to 75 gallons of dilute spray per acre. Use as a broadcast treatment when existing grass should be suppressed and as a band treatment when recovery of existing grass is desired.
	0.25-0.50 (2 lb/gal SC/L)	Use limited to east of Rocky Mountains. Broadcast or band. Apply prior to or at time of seeding grasses or forage legumes such as alfalfa, clover and birdsfoot trefoil. Apply only to pastures grazed or mowed to no more than 2 to 3 inches in height.
	0.25-0.50 (2 lb/gal SC/L)	Use limited to west of Cascade and Sierra Nevada Mountains. Broadcast or band. Apply prior to or at time of seeding grasses such as hardinggrass and palestine orchardgrass. Apply in October through December after first fall rains and after weeds have emerged. Apply on moderate to heavily grazed areas. Do not use in areas with heavy sod and weed growth.
	Raspberry	See Blackberry cluster.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/13023AA	Rhubarb	0.05 (N) ppm Do not graze treated areas. General Information: Do not apply more than 2 applications per season.
	0.50-1.00 (2 lb/gal SC/L)	Dormant application. Apply before crown buds begin to grow. Apply 50 to 150 gallons of spray mix per acre.
/27008AA	Safflower	0.05 (N) ppm (seed)
	0.12-0.25 (2 lb/gal SC/L)	Use limited to CA. For control of emerged volunteer barley. Preplant. Broadcast. Apply by air in 5 to 10 gallons of water per acre. Apply to preformed seedbeds.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.
/28019AA	Sorghum	0.05 (N) ppm (forage, grain)
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit minimum weed emergence. Seeding should be done with a minimum of soil disturbance.
/24006AA	Sorghum (grain crop)	0.05 ppm (forage, grain)
	0.25-0.50 (2 lb/gal SC/L)	Preemergence. Broadcast. Tank mix with atrazine.
	0.25-0.50 (2 lb/gal SC/L)	Preplant or preemergence. For control of barnyardgrass, crabgrass, and fall panicum. Tank mix with atrazine and terbutryn. Apply in 20 to 60 gallons of water per acre. Use where sorghum will be planted directly into previous crop residues.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Sorghum (grain crop) (continued)	
	0.25-0.50 (2 lb/gal SC/L)	Postemergence. Directed spray or band treatment between the crop rows. For control of crabgrass and pigweed 3 inches or less in height. Treat when crop is at least 12 inches tall. Use the lower rate for weeds less than 2 inches tall and the higher rate for weeds 2 to 3 inches tall. Apply in 20 to 40 gallons of water per acre. Apply so that only the lower 3 inches or less of sorghum stalk is sprayed.
/28023AA	Soybeans	0.05 (N) ppm (soybeans and forage) Postemergence directed spray: Do not graze treated areas or feed treated forage to livestock. Preharvest broadcast: Do not pasture livestock within 15 days after treatment. Remove livestock from treated fields at least 30 days before slaughter. Do not use treated vines for feed or forage. General Information: Apply in 20 to 60 gallons of water per acre by ground or 2 to 10 gallons by air. Seeding should be done with a minimum of soil disturbances.
	0.25-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Use the lower rate when spring weeds are less than 4 inches high or when a directed spray or cultivation will be used within 3 weeks after planting. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence.
	0.25-0.50 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast. For use in minimum tillage systems. Tank mix with alachlor and linuron.
	0.25 (2 lb/gal SC/L)	Preemergence. Broadcast or band. Tank mix with linuron. For use where soybeans will be planted directly into preformed bed, cover crop, or in previous crop residues.

OR

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PARAQUAT DICHLORIDE

Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
Soybeans (continued)	
0.25-0.50 (2 lb/gal SC/L)	Preemergence. Broadcast. Tank mix with metribuzin. For preemergence control of smartweed, pigweed, and cocklebur. Use the higher dosage if weeds are 4 to 6 inches tall.
	OR
0.25-0.50 (2 lb/gal SC/L)	Preemergence. Broadcast. Tank mix with alachlor and metribuzin. For preemergence control of smartweed, pigweed, cocklebur, foxtail, and crabgrass. Use the higher dosage if weeds are 4 to 6 inches tall.
0.25-1.00 (2 lb/gal SC/L)	Preemergence. Broadcast. Tank mix with pendimethalin and metribuzin or linuron and metribuzin. Use the higher dosage for dry conditions or when weeds are 3 to 6 inches tall.
0.25-0.50 (2 lb/gal SC/L)	Preemergence. Broadcast. Tank mix with oryzalin and metribuzin.
0.063-0.125 (2 lb/gal SC/L)	Postemergence. Directed spray or directed band application between crop rows. Use the lower rate for control of seedling johnsongrass, crabgrass, goosegrass, brachiaria, Texas millet and pigweed less than 2 inches tall. Use the higher rate for weeds 2 to 4 inches tall. Do not treat if crop is less than 8 inches tall. Retreat after 7 to 14 days if needed. Do not treat more than twice.
0.12-0.25 (2 lb/gal SC/L)	Preharvest. Broadcast. Apply when soybean plants are mature. Use the higher rate for control of cocklebur.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Soybeans (continued)	
	[SLN] 0.12 (2 lb/gal SC/L)	SLN - Use limited to AR. Postemergence. Directed spray or band treatment. For control of annual broadleaf weeds 2 to 3 inches tall and grasses 2 to 4 inches tall. Apply the first spray when soybeans are 8 inches tall and a second spray 7 to 14 days later. Apply 20 gallons of finished spray per acre to the lower 3 inches of the soybean plant. A non-ionic surfactant may be applied to the finished spray. Do not apply more than 2 applications per year.
	Squash	See Beans (lima) cluster.
/01016AA	Strawberries	0.25 ppm Do not graze livestock in treated areas. 21 day preharvest interval. Do not apply more than 3 times per season.
	0.5 (2 lb/gal SC/L)	Postemergence. Directed spray. Apply in 20 to 60 gallons of water per acre. Use ground equipment directing spray between the rows.
/25002AA	Sugar Beets	0.5 ppm (sugar beets and tops)
	0.12-0.25 (2 lb/gal SC/L)	Use limited to CA. For control of emerged volunteer barley. Preplant. Broadcast. Apply by air in 5 to 10 gallons of water per acre. Apply to preformed seedbeds.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/25003AA	Sugarcane	0.5 (N) ppm Postemergence directed spray in LA: 30 day preharvest interval. General Information: When using directed sprays, apply when weeds are 2 to 6 inches high. Avoid contact with cane foliage. Make a second and final application, if necessary, when new growth is 2 to 6 inches high.
	0.25-0.50 (2 lb/gal SC/L)	Use limited to LA. Postemergence. Directed spray. Apply in 20 to 200 gallons of water per acre. For tiller control, apply when tillers are less than 18 inches high. Use the higher rate with heavier weed growth or tiller growth.
	0.50 (2 lb/gal SC/L)	Use limited to FL. Postemergence. Directed spray. Apply in 50 to 100 gallons of water per acre. Apply early in the season (March to April). Do not apply after June 1st, as cane growth may be stunted and yield reduced.
	0.50 (2 lb/gal SC/L)	Use limited to HI. Postemergence. Directed spray. Apply in 20 to 200 gallons of water per acre. Do not apply after cane rows have closed in.
	0.12-0.25 (2 lb/gal SC/L)	Use limited to FL and TX. Preharvest desiccation. Broadcast. Apply by air in 4 to 10 gallons of water per acre. Apply to mature plant or stubble cane. Use the higher rate under cool, cloudy conditions. Apply 3 to 14 days before burning and harvest. For best results, apply when the weather is clear and warm.
/27011AA	Sunflower (oil crop)	2 ppm (seeds) Do not graze treated areas or feed treated forage to livestock.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Sunflower (oil crop) (continued)	
	0.25-0.50 (2 lb/gal SC/L)	Preharvest desiccation. Broadcast. Apply when sunflower seeds reach physiological maturity and harvest 7 to 21 days after application. Apply in 20 to 40 gallons of water per acre by ground or 5 gallons by air. Use the higher rate when crop stands or weed infestations are heavy.
/11005AA	Tomato	0.05 ppm (vegetables, fruiting)
	0.12-0.25 (2 lb/gal SC/L)	Use limited to CA. For control of emerged volunteer barley. Preplant. Broadcast. Apply by air in 5 to 10 gallons of water per acre. Apply to preformed seedbeds.
	0.50-1.00 (2 lb/gal SC/L)	Preplant or preemergence. Broadcast or band. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.
	0.50 (2 lb/gal SC/L)	Use limited to Middle Atlantic, Southeast, South Central regions and Southwest to the Western boundary of TX. Postemergence. Directed spray. Band application between the rows. Apply in 20 to 100 gallons of water per acre. Use shields to protect crop plants. Can be used between plastic mulch covered rows. Do not make more than 3 applications per crop season.
	Turnips	See Beans (lima) cluster.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/03009AA	Walnut	0.05 (N) ppm (nuts) Make only 1 application per year. Apply only in orchards where trees have been established 1 year or more. General Information: Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees.
	0.5-1.00 (2 lb/gal SC/L)	Directed spray. Apply in 30 to 150 gallons of water per acre.
	0.5-1.00 (2 lb/gal SC/L)	Use limited to CA. Directed spray. Tank mix with simazine. Apply in 50 to 200 gallons of water per acre. Use the lower dosage on coarse textured or low organic matter soils, and the higher dosage on fine textured or higher organic matter soils. Do not apply to sandy soil.
	Watermelon	See Beans (lima) cluster.
/28065AA	Wheat	0.05 (N) ppm (grain) Do not graze treated areas.
	0.25-1.00 (2 lb/gal SC/L)	Broadcast or band. Preplant or preemergence. Apply in 20 to 60 gallons of water per acre by ground or in 5 to 10 gallons of water per acre by air. Seedbeds should be formed as far ahead of planting and treatment as possible to permit maximum weed emergence. Seeding should be done with a minimum of soil disturbance.

(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)

/66002AA	Fallowland	
	0.25-0.5 (2 lb/gal SC/L)	Broadcast. Apply to postharvest wheat stubble. Use 20 to 60 gallons of water by ground or in 5 to 10 gallons of water per acre by air. Add a non-ionic surfactant. May be tank mixed with 2,4-D or banvil.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	TERRESTRIAL NONFOOD CROP	
	(Ornamental Plants and Forest Trees)	
	General Warnings and Limitations: Do not use around home gardens, schools, recreational parks or playgrounds.	
/35094AA	Apple (ornamental)	
/35021AA	Arborvitae	General Information: Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees.
/35022AA	Ash	
/35095AA	Citrus (ornamental)	
/38049AA	Elm	
/35352AA	Filbert (ornamental)	
/35051AA	Fir	
/35052AA	Flowering Almond	
/35053AA	Flowering Apricot	
/35055AA	Flowering Cherry	
/35058AA	Flowering Peach	
/35059AA	Flowering Pear	
/35060AA	Flowering Plum	
/35093AA	Oak	
/35367AA	Olive (ornamental)	
/35098AA	Pine	
	0.50-1.00 (2 lb/gal SC/L)	Directed spray. Apply in 30 to 150 gallons of water per acre. Retreatment or spot treatment may be necessary for hard-to-kill weeds.
/330100A	Ornamental Lawns	
/320000A	Ornamental Plants (flower beds and foundation plantings)	General Information: Treated areas may be reseeded 24 hours after application.
/350000A	Ornamental Trees	
/340040A /670110A	Ornamental Woody Shrubs	
	[MAI] -- (0.276% PrL)	Edging and spot treatment. Directed spray. Spray weeds thoroughly. Repeat application when necessary. Formulated with petroleum distillates.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
/35353AA	Pecan (ornamental)	General Information: Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees.
	0.50-1.00 (2 lb/gal SC/L)	Directed spray. Apply in 30 to 50 gallons of water per acre. Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees. Retreatment or spot treatment may be necessary for hard-to-kill weeds.

(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)

General Warnings and Limitations: Do not use around home gardens, schools, recreational parks or playgrounds.

/670130A /670000A	Rights-of-Way	General Information: Rights-of-Way include highway, railroad, and utility (transfer station and substation) rights-of-ways.
	0.50-1.00 (2 lb/gal SC/L)	Broadcast. Apply in 50 to 100 gallons of water per acre. Repeat as needed for control of mature woody weeds. Avoid spray contact with foliage or fruit of food crops and ornamentals.
/670000A	Uncultivated Non-agricultural Areas	General Information: Uncultivated Non-agricultural Areas include areas around commercial buildings, fencerows, storage yards, public airports, electric transformer stations and substations, and pipeline pumping stations. Refer to Rights-of-Way for dose and use patterns.
/670110A	Walks, Driveways and Posts	Refer to TERRESTRIAL NONFOOD CROP, (Ornamental Plants and Forest Trees), Ornamental Lawns cluster for dosage and use patterns.

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	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	FORESTRY	
	General Warnings and Limitations: Do not use around home gardens, schools, recreational parks or playgrounds. Do not allow animals to graze on treated areas.	
/30019AA	Arborvitae (shelterbelt)	General Information: Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees.
/30042AA	Elm (shelterbelt)	
/30043AA	Fir (shelterbelt)	
/30057AA	Oak (shelterbelt)	
/30058AA	Pecan (shelterbelt)	
/30059AA	Pine (shelterbelt)	
	0.50-1.00 (2 lb/gal SC/L	Directed spray. Apply with a non-ionic surfactant in 50 to 200 gallons of water per acre. Do not allow spray to contact green stems, fruit or foliage. Use a shield when spraying around young trees. Retreatment or spot treatment may be necessary for hard-to-kill weeds.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
35098AA	Pine (Loblolly, Longleaf, Pitch, Pond, Shortleaf, Slash, Spruce, Virginia)	General Information: Select trees from sites not subject to periods of extreme drought and from vigorous, non-stagnated stands either natural or planted. In stagnated stands or commercial timber stands, do not treat sooner than 3 years after commercial thinning. Resin soaking can occur from treatments made any time of the year, however, cool season treatments under non-drought conditions are recommended. The interval between application and tree harvest should be at least 6 months, preferably 12 to 24 months. Treatment may encourage beetle attack or cause premature death of tree. Desiccation of xylem tissue, rather than resin soaking, is more likely at higher dosages. Treatment can result in reduced stem growth.
	0.30-5.00% cation (wt/wt) (2 lb/gal SC/L)	Bore-hole application. Plant regulator (resin soaking). Bore 0.38 to 0.62 inch holes 2 to 6 inches deep, depending on tree diameter, sloping slightly downward rather than directly towards center of tree. Lower concentrations are usually applied at higher volumes of 15 to 35 milliliters per tree, resulting in application of 45 to 100 milligrams per tree. Using 2 to 4 percent solutions and applying 5 milliliters per single hole per tree results in application of 100 or 200 milligrams per tree. Forty-five to 100 milligrams per tree have resulted in effective oleo-resin induction.
	1.00%-4.00% cation (wt/wt) (2 lb/gal SC/L)	Tree injection. Plant regulator (resin soaking). Injections should be made beneath bark and just beneath cambium layer. Make injections 1 to 2 inches apart around one-third of tree circumference, or no closer than 3 inches apart all around tree. Apply 0.2 to 0.4 milliliters per injection. Using 2 to 4 percent solution results in 36 to 144 milligrams chemical applied per 9 inch diameter tree, for holes spaced 1 inch apart around one-third of tree or 3 inches apart all around tree.

	Site, Dosage and Formulation (lb cation/A)	Tolerance, Use, Limitations
	Pine (continued)	
	1.00%-5.00% cation (wt/wt) (2 lb/gal SC/L)	Bark cut treatment. Plant regulator (resin soaking). Remove a 1 inch wide streak of bark about 1 to 2 feet from ground level. Total length should not exceed one-third of tree circumference. Apply spray to exposed xylem to run-off. For a 9 inch diameter tree, 3 milliliters of spray will cover the streak. Using 3 milliliters of 2 to 4 percent solution will result in applications of 60 to 120 milligrams of chemical per streak.
	AERIAL AND TANK MIX APPLICATIONS	
9001500 AAAAAAA	Aerial Application	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Alfalfa, Barley, Clover, Corn, Cotton, Lettuce, Melons, Peppers, Potato, Safflower, Sorghum, Soybeans, Sugar Beet, Sugarcane, Sunflower (oil crop), Tomato, Wheat
9900300 AAAAAAA	Tank Mix	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Alfalfa, Asparagus, Apple, Corn, Corn (Field), Cotton, Peach, Pear, Peppermint (Spearmint), Sorghum (grain crop), Soybeans, Walnuts (Noncrop, Wide Area, and General Indoor/Outdoor Treatments) Fallowland

EPA Compendium of Acceptable Uses

PARAQUAT DICHLORIDE

Listing of Registered Pesticide Products by Formulation

&029.1002 29.1% formulation intermediate
paraquat dichloride (061601)
010182-00113

&043.5002 43.5% formulation intermediate
paraquat dichloride (061601)
010182-00115

&102.0015 2 lb/gal soluble concentrate/liquid
paraquat dichloride (061601)
010182-00074 010182-00111 010182-00112 051036-00077

(010182-00111) AL860002 AR790008

&220.4015 20.4% soluble concentrate/liquid
paraquat dichloride (061601)
010182-00103*
*jacket currently unavailable for review.

&200.2819 0.276% pressurized liquid
paraquat dichloride (061601) plus petroleum distillates (063503)
010182-00114

9999999 State Label Registrations

CA Reg. No.
000239-04224

HI Reg. No.
037843-08551

EPA Compendium of Acceptable Uses

PARAQUAT DICHLORIDE

Appendix A-1

Listing of Active Ingredient(s) Found in Combination with the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
063503	petroleum distillate	--

-- Use Common Name

EPA Compendium of Acceptable Uses

PARAQUAT DICHLORIDE

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
100101	cyanazine (ISO)	2-[[4-chloro-6-(ethylamino)-S-triazin-2-yl]-amino]-2-methyl propionitrile
030001	2,4-D	2,4-dichlorophenoxy-acetic acid
029801	dicamba	--
101101	metribuzin	4-amino-6-(1,1-di-methylethyl)-3-(methylthio)-1,2,4-triazin-5(4H)-one

-- Use Common Name

APPENDIX IV

BIBLIOGRAPHY

BIBGUIDE-1

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

  (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

  (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

  (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

  (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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00015752	Kern, C.L.; Staniforth, D.; Slagowski, J.L. (1978) Metolachlor (Dual(R) 8E); Atrazine (AAtrex(R) 80W or 4L); Paraquat (Paraquat CL): AG-A No. 5000 I,II (Unpublished study received Mar 16, 1979 under 100-583; prepared in cooperation with Iowa State Univ., EN-CAS Laboratories and Chevron Chemical Co., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237819-H)
00015768	Kincaid, L.; Slagowski, J.L. (1978) Metolachlor + Linuron + Paraquat; Dual 8E + Lorox 50W + Paraquat 2CL: AG-A No. 4762 I,II. (Unpublished study including letter dated May 23, 1978 from J.D. Riggleman to Robert A. Kahrs, received Mar 16, 1979 under 100-583; prepared in cooperation with Chevron Chemical Co. and E.I. du Pont de Nemours & Co., Inc., submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:237821-J)
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APPENDIX V

FORMS

OMB Approval No 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date ___________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

OMB Approval No. 2070-0057
Expiration Date 11/30/89

"GENERIC" DATA EXEMPTION STATEMENT

EPA Product Registration Number: ____________

Registrant's Name and Address: ______________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient __________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ________________ and their registration number(s) is/are ____________

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ______________________
(Signature)

Dated: ______________ ______________________
(Typed)

EPA Form 8570-27